UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

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In Re: Bard IVC Filters Products Liability Litigation	MD-15-02641-PHX-DGC
	Phoenix, Arizona
	May 15, 2018
Doris Jones, an individual, Plaintiff,	1:11 p.m.
	CV 16-00782-PHX-DGC
vs.	
C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

(*Jury Trial - Day 1 - P.M. Session*)
(*Pages 125 through 230, inclusive.*)

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I N D E X

P R O C E E D I N G S

THE COURT: Ladies and Gentlemen, you are now the jury in this case, and it is my duty to instruct you on the law. It is your duty to find the facts from all the evidence that will be presented during the trial. To those facts you will apply the law as I give it to you. 01:11PM

You must follow the law as I give it to you, whether you agree with it or not. And you must not be influenced by any personal likes or dislikes, opinions, prejudices, or sympathy. That means that you must decide the case solely on the evidence that you hear during the trial. You have taken an oath promising to do so. 01:12PM

At the end of the trial I will give you some final instructions. Those final instructions will be more detailed discussions of the law and will govern your actual deliberation in the case. 01:12PM

Please do not read into any instructions I give or into anything else I may say or do during the trial that I have an opinion regarding the evidence or an opinion about what your verdict should be. 01:12PM

To help you follow the evidence, I will give you a brief summary of the positions of the parties. This is a personal injury case against a medical product manufacturer. The plaintiff, Doris Jones, a 53-year-old woman, had a Bard Eclipse Filter placed in her inferior vena cava, the vein that 01:13PM

carries the blood back to the heart. You will hear these filters referred to as IVC filters or inferior vena cava filters. An IVC filter is intended to catch blood clots before they reach the heart or lungs. The defendants in this case, C.R. Bard, Inc., and Bard Peripheral Vascular, designed, manufactured, and sold the Eclipse Filter Mrs. Jones received. 01:13PM

Mrs. Jones alleges that the filter was defectively designed and the defendants failed to warn about its risks. She alleges that she was injured by the filter, and she seeks to recover money from the defendants to compensate for her injuries and to punish defendants for their allegedly wrongful conduct. 01:14PM

Defendants deny that their filter was defectively designed or that they failed to warn of its risks. Defendants contend that the risks associated with Bard IVC filters are understood by the medical community. Defendants assert that they are not responsible for any injuries or damages suffered by Mrs. Jones. 01:14PM

Although there are two defendants in this case, C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., you should decide this case as to the two defendants jointly. As a result in the instructions I give you and the verdict form that you see at the end of the case and even during some of the discussion during the trial, we likely will just refer to the defendants collectively as "Bard." Unless otherwise stated, 01:14PM 01:15PM

any instructions I give you therefore apply to both of the defendants.

The evidence you are to consider in deciding what the facts are will consist of the sworn testimony of the witnesses; the exhibits that are admitted into evidence; any facts to which the lawyers have agreed, and those will be clearly identified for you as stipulated or agreed-upon facts; and any facts that I might instruct you to accept as proven. 01:15PM

In reaching your verdict, you may consider only the testimony and exhibits received into evidence or the facts that have been agreed to. Certain things are not evidence, and you may not consider them in deciding what the facts are. I will list them for you. 01:15PM

First, arguments and statements by lawyers are not evidence. The lawyers are not witnesses. What they may say in their opening statements, closing arguments, and at other times is intended to help you interpret the evidence but it is not evidence. If the facts as you remember them differ from the way the lawyers have stated them, your memory of them controls. 01:16PM

Second, questions and objections by lawyers are not evidence. Attorneys have a duty to their clients to object when they believe a question is improper under the Rules of Evidence. You should not be influenced by a lawyer's objection or by my ruling on it. 01:16PM

Third, any testimony that is excluded or stricken or 01:16PM

that I instruct you to disregard is not evidence and must not be considered. In addition, some evidence may be admitted only for a limited purpose. If so, I will give you an instruction that this evidence is coming in only for a limited purpose, and you must consider it only for that purpose and not for any other. 01:17PM

Fourth, anything you may see or hear when the Court is not in session is not evidence. You are to decide the case solely on the evidence that is received during the trial.

Evidence may be direct or circumstantial. Direct evidence is direct proof of a fact such as testimony by a witness about what that witness personally saw or heard or did. Circumstantial evidence is proof of one or more facts from which you can find another fact. You should consider both kinds of evidence. The law makes no distinction between the weight to be given to either direct or circumstantial evidence. It is for you to decide how much weight to give to any evidence. 01:17PM 01:17PM

There are rules of evidence that control what can be received into evidence during the trial. When a lawyer asks a question or offers an exhibit into evidence and the lawyer on the other side thinks it is not permitted by the rules of evidence, that lawyer may object. If I overrule the objection, the question may be answered or the exhibit may be received in evidence. If I sustain the objection, the question cannot be 01:18PM 01:18PM

answered and the exhibit cannot be received in evidence.

Whenever I sustain an objection to a question, you should disregard the question and must not speculate or guess at what the answer might have been.

As indicated earlier, sometimes I may order that evidence be stricken from the record or that you disregard something that actually was presented during the trial. That means that when you are deciding the case, you must not consider the stricken evidence for any purpose. 01:18PM

In deciding the facts in this case, you may have to decide which testimony to believe and which testimony not to believe. You may believe everything a witness says or part of it or none of it. In considering the testimony of any witness, you may take into account the opportunity and ability of the witness to see or hear or know the things testified to; the witness's memory; the witness's manner while testifying; the witness's interest in the outcome of the case, if any; the witness's bias or prejudice, if any; whether other evidence contradicted the witness's testimony; the reasonableness of the witness's testimony in light of all the evidence; and any other factors that bear on believability. 01:18PM 01:19PM 01:19PM

Sometimes a witness may say something that is not consistent with something else he or she said. Sometimes different witnesses may give different versions of what happened. People often forget things or make mistakes in what 01:20PM

they remember. Also two people may see the same event but remember it differently.

You may consider these differences, but do not decide the testimony is untrue just because it differs from some other testimony. However, if you decide that a witness has deliberately testified untruthfully about something important, you may choose not to believe anything the witness said. On the other hand, if you think the witness testified untruthfully about some things but told the truth about others, you may accept the part you think is true and ignore the rest. 01:20PM

The weight of the evidence as to a fact does not necessarily depend on the number of witnesses who testify about that fact. What is important is how believable the witnesses are and how much testimony -- pardon me -- how much weight you think their testimony deserves. 01:20PM

I will now say a few words about your conduct as jurors. First, please keep an open mind throughout the trial and do not decide what the verdict should be until you and your fellow jurors have completed your deliberations at the end of the case. 01:21PM

Second, because you must decide this case based only on the evidence received in the trial and on my instructions as to the law that applies, you must not be exposed to any other information about the case or to the issues it involves during the course of your jury duty. Thus, until the end of the case 01:21PM

or unless I tell you otherwise, do not communicate with anyone in any way, and do not let anyone else communicate with you in any way about the merits of the case or anything to do with it.

This includes discussing the case in person, in writing, by phone or electronic means via e-mail, text messaging, or any internet chat room, blog, website, or application, including but not limited to Facebook, YouTube, Twitter, Instagram, LinkedIn, Snapchat, or any other forms of social media. 01:21PM

That's a new instruction, but we have to be very specific. 01:22PM

This applies to communicating with your fellow jurors until I give you the case for deliberation. And it applies to communicating with everyone else, including your family members, your employer, the media or press, and the people involved in the trial although you obviously can notify your family and your employer that you have been seated as a juror in this case. 01:22PM

But if you are asked or approached in any way about your jury service or anything about this case, please respond that you have been ordered not to discuss the matter, and please report that contact to me immediately. 01:22PM

Because you will receive all of the evidence and legal instruction you properly may consider to return a verdict during the course of this trial, do not read, watch, or listen 01:23PM

to any news or media accounts or commentary about the case or anything to do with it. Do not do any research such as consulting dictionaries, searching the internet, or using other reference materials. And do not make any investigation or in any other way try to learn about the case on your own. 01:23PM

Do not visit or view any place discussed in this case and do not use internet programs or other devices to search for or view any place discussed during the trial.

Also, do not do any research about this case, the law, or the people involved in the case including the parties, the witnesses, or the lawyers until you have been excused as jurors. 01:23PM

If you happen to read or hear anything touching on this case in the media, please turn away immediately, and please report it to me as soon as possible. 01:24PM

These rules protect each party's right to have this case decided only on the evidence that has been presented here in court. Witnesses in court take an oath to tell the truth, and the accuracy of their testimony is tested through the trial process. 01:24PM

If you do any research or investigation outside the courtroom or gain any information through other kinds of communications, then your verdict may be influenced by inaccurate, incomplete, or misleading information that has not been tested by the trial process. Each of the parties is 01:24PM

entitled to a fair trial by an impartial jury, and if you decide the case based on information that was not presented here in court, you will have denied the parties a fair opportunity to address that evidence and to discuss how it affects the case. 01:24PM

Remember, you have taken an oath to follow the rules and it is very important that you follow these rules. A juror who violates these restrictions jeopardizes the fairness of these proceedings, and a mistrial could result that would require the entire trial process going clear back to the jury questionnaires weeks ago to start over again. 01:25PM

If any of you is exposed to any outside information, please notify me about it immediately. And if that happens you can simply tell Traci or Nancy, and they will get it to my attention right away. 01:25PM

I urge you to pay close attention to the trial testimony as it is given. You will not have a transcript of what is said during your deliberations as a jury. Now, you might wonder why that is if it's all being taken down by the court reporters, but the answer is it takes them time to go through the transcript, clean it up, and make sure it's complete and that process will not be finished by the time you are deliberating. So you will not have a transcript. You will need to rely upon your memory of the testimony. 01:25PM

If you wish, you may take notes to help you remember 01:26PM

the evidence. If you do take notes, please keep them to yourself until you go to the jury room to decide the case. Please do not let notetaking distract you. When you leave the courtroom at a break or at the end of the day, your notes should be left on your chair here in the courtroom. Nobody will read your notes. 01:26PM

Whether or not you take notes you should rely on your own memory of the evidence. Notes are only to assist your memory. You should not be overly influenced by your notes or those of the other jurors. And I will mention that after the trial is over, your notes will be destroyed. They won't be retained as any sort of a record. 01:26PM

From time to time during the trial, it may become necessary for me to talk with the attorneys outside of the jury's hearing either by having a conference at the bench as we did a couple of times during jury selection or perhaps even by calling a recess and excusing you from the courtroom. Please understand that while we are having these conferences, we are working and not just trying to keep you waiting. The purposes of these conferences are to keep -- are not to keep relevant information from you but are to decide how evidence is to be treated under the rules of evidence and to avoid confusion and error. 01:26PM 01:27PM

We will do what we can to keep the number and length of these conferences to a minimum. I may not always grant a 01:27PM

lawyer's request for a conference. Please do not consider my granting or denying their request for a conference as any indication of my opinion of the case or of what your verdict should be.

Trials proceed in the following way: First, each side may make an opening statement. An opening statement is not evidence. It is simply an outline to help you understand what that party expects the evidence will prove. A party is not required to make an opening statement. 01:27PM

The plaintiff will then present evidence and counsel for the defendant may cross-examine. Then the defendant may present evidence, and counsel for the plaintiff may cross-examine. After the evidence has been presented, I will give you instructions on the law that applies to the case and the attorneys will then make closing arguments. After that you will go to the jury room to deliberate on your verdict. 01:28PM 01:28PM

Counsel, are there any corrections or additions to the instructions?

MR. O'CONNOR: Nothing from the plaintiffs, Your Honor. 01:28PM

MR. NORTH: Nothing, Your Honor.

THE COURT: All right. Ladies and Gentlemen, before we have the opening statements, the lawyers have agreed that I should read to you some facts to which both sides agree. These are stipulated facts. And so you can treat these facts as 01:29PM

having been proved. They are sort of general background facts, but it will save some time in the presentation of the evidence.

The defendants in this case are C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., sometimes referred to as BPV.

BPV is a wholly-owned subsidiary of C.R. Bard, Inc., 01:29PM
the parent company. As indicated throughout this case, we may just refer to the defendants collectively as Bard or sometimes as defendants.

The product that is the subject of this case is the Bard Eclipse IVC Filter. It was designed, manufactured, 01:29PM
marketed, and sold by Bard. The Eclipse Filter is a conical -- is conical in shape and consists of a main shaft which 12 struts, six of which are called arms and six of which are called legs, are attached. And you will see examples of that.

The Eclipse Filter is constructed of a nickel titanium 01:30PM
alloy called Nitinol. The Eclipse filter is a medical device that is implanted in the inferior vena cava, which is the largest vein in the human body. The United States Food and Drug Administration cleared the Eclipse Filter for commercial availability through what is known as the 510(k) process 01:30PM
outlined in the Food, Drug, and Cosmetic Act.

The Eclipse filter was cleared for a commercial availability in the United States for use in patients as a permanent filter with an optional retrievable procedure on January 14, 2010. Bard marketed the Eclipse filter for both 01:31PM

permanent and optional retrievable placement.

On August 24th of 2010, a vascular surgeon by the name of Dr. Anthony James Avino, A-V-I-N-O, implanted an Eclipse IVC filter in the plaintiff in this case, Mrs. Jones, at Memorial Health University Medical Center in Savannah, Georgia. 01:31PM

Mrs. Jones was properly indicated for placement of the Eclipse filter on August 24th, 2010. Dr. Avino's placement of the Eclipse filter in Mrs. Jones was appropriate and met the applicable standard of care for doctors in his position.

Dr. Avino did not cause, contribute to, and was not a factor in producing any of the injuries claimed by Mrs. Jones in this lawsuit. 01:31PM

Subsequent to implantation and after August 14th, 2013, Mrs. Jones' Eclipse filter fractured, and a strut embolized to her right pulmonary artery. On April 22nd, 2015, a chest X-ray and CT angiogram revealed that Mrs. Jones' Eclipse filter had fractured and the fractured strut had embolized to her right pulmonary artery. 01:32PM

On April 23rd, 2015, Dr. Kirsten Nelson removed Mrs. Jones' Eclipse filter through a percutaneous procedure. Dr. Nelson's actions in retrieving the Eclipse filter from Mrs. Jones' IVC were appropriate and met the applicable standard of care for doctors in her position. 01:32PM

Dr. Nelson's decision not to attempt to retrieve the Eclipse filter fragment from Mrs. Jones' pulmonary artery was 01:33PM

appropriate and met the applicable standard of care for doctors in her position. Dr. Nelson did not cause, contribute to, and was not a factor in producing any of the injuries claimed by Mrs. Jones in this lawsuit.

The broken strut of the Eclipse filter remains in Mrs. Jones' right pulmonary artery. Mrs. Jones has not sought or received any medical care since March 16th, 2016. 01:33PM

Counsel, any additions or corrections to the stipulated facts?

MR. O'CONNOR: Nothing from plaintiff. 01:33PM

MR. NORTH: Nothing from defendants, Your Honor.

THE COURT: Okay. We will then proceed with the plaintiff's opening statement.

MR. O'CONNOR: Thank you, Your Honor. May it please the Court, good afternoon. 01:34PM

As you just heard, members of the jury, on August 24th, 2010, Doris Jones was implanted with a Recovery -- excuse me -- a Bard Eclipse IVC filter. And that Eclipse filter would go on to break, fracture, and migrate up her vena cava through her heart and into her pulmonary artery, the Eclipse filter. 01:35PM

And this case doesn't start then in August 2010. It actually starts much earlier, several years earlier, as a matter of fact. It starts in about 1999, 2000. You see, Bard wanted to be first in a new competitive market, a very exciting market, a market that had the potential for profitability. 01:35PM

Bard wanted to be first to the market for retrievable filters, filters that would not remain permanent in a patient but that could be retrieved by the doctors.

And the evidence in this case will show to get there, to get to that market and be first, that Bard didn't rely on science. Bard didn't rely on long term clinical studies. In fact, the evidence will show that Bard didn't even rely on accurate testing. What Bard relied on to get to that competitive market was aggressive marketing. And that's what the evidence will show. 01:36PM

Now, the evidence will also show that the choices that Bard made were harmful and caused serious harm to patients, including Doris Jones.

You, as members of this jury, will see documents. You will hear testimony for the first time that nobody heard back in the era that Bard was developing, beginning with the Recovery, through the generations of filters, including the Eclipse. You will see documents that Bard didn't even share with doctors, the FDA, or even its sales force. And the evidence will show you the choices Bard made to win that race to the market. 01:37PM

Now, what I'm going to do here is just stop for a moment. I just want to talk to you about IVC filters.

THE COURT: Mr. O'Connor, let me just interrupt for a moment. Is that up on each of your screens, Ladies and 01:37PM

Gentlemen? Okay. Go ahead, Mr. O'Connor.

MR. O'CONNOR: So what you are seeing is a very simplified diagram of the anatomy, the vena cava, inferior vena cava. That's where filters are implanted. And you will see, as you can see it's right next to the aorta. In addition the vena cava is adjacent to very vital, important organs. The theory behind an IVC filter is that it can be implanted, they say percutaneously, a retrievable, that is, and sit in the vena cava. It should remain centered and remain fixed to the side of the walls of the vena cava, and the theory is that it should trap clots or deep vein thrombosis, clots that start somewhere usually in the lower extremity and stop them so they don't go to the lungs. 01:38PM 01:38PM

Now, for decades before this race to the market there were permanent filters. Next slide. 01:39PM

And you are going to hear about the Simon Nitinol Filter. It was a permanent filter, one that was intended to remain in the patient for the remainder of his or her life. And this was a filter that you will find had a very good track record according to Bard itself. Bard acquired the technology from a company called NMT, and with that came an engineer, Robert Carr, and you will hear from him. 01:39PM

And again, the Simon Nitinol, for years, had a very impressive safety record and that's confirmed by testimony you will hear in this case. And that's from Bard's own medical 01:39PM

director, Dr. Ciavarella.

So Bard had an opportunity to be the first to the market of a new competitive market, like I said, the retrievable filters. And as Bard knows, in competition, the first to the market has a good shot of getting the market share. They did everything they could to win the race. 01:40PM

What was going on at this time early in the 1999/2000 period is that the Recovery Filter was being developed. And NMT, Nitinol Medical Technologies, had plans. What they planned to do was develop the first retrievable filter and have a clinical trial in Europe to establish substantial equivalence. And that's with respect to the issue of safety and effectiveness. That's the process that a device like the filter has to go through to be cleared in the FDA, not approved. And that's important. We're going to talk about that in a moment. 01:41PM

Next. So here is a preview of how Bard proceeded. You are going to see that the Simon Nitinol Filter started the process. It's called a predicate device. And to bring a new device to the market, a company like Bard needs to show a substantial equivalence. The Recovery was cleared eventually, and we'll talk about that. First is a permanent device with the intent to eventually become retrievable. But the evidence will show that the Recovery was never tested in a long term clinical trial to evaluate whether it was safe and effective in 01:41PM 01:42PM

humans for the long term. As a matter of fact, what the evidence will show is that the first time the Recovery was tested in any type of long term period is when it was released to the market. When it was released to the market for doctors to implant in patients is when the first time this device had any long term experience in human beings. And that choice would begin a cascade of problems with patients. 01:42PM

Because without knowing the long term safety and efficacy of the Recovery Filter, that being Bard's choice, the filter resulted in a number of failures, failures that caused serious harm to people. 01:43PM

Now, to stay in the marketplace, to stay in this competitive market, rather than stop sales, as you will learn from the evidence, of the Recovery, when Bard became aware early on that it had problems, Bard decided to modify it. And so the next iteration you will hear about was known internally as the Recovery G2, or the Modified Recovery, but it was called the G2. And we'll talk about that in more detail. 01:44PM

And then after the G2, well, when the G2 came into the market, guess what happened? Without any long term clinical studies, without the right testing, the G2 also experienced many, many failures in patients. Bard eventually modified the tip of the G2, and you can see a hook. It was the G2 with a hook so that doctors could eventually retrieve it in a way using that hook as opposed to going in with a device that would 01:44PM 01:45PM

pull it from the cap. But the failures continued.

And so the evidence will show you to stay on the market, Bard decided to get rid of the baggage, the baggage that had been created by these filters, predicate filters, and that's how it developed the Eclipse, which the evidence will show you is essentially the G2 with some modifications. 01:45PM

And what you are seeing on your screen is the history of the Bard filters up to the Eclipse, which is the filter that Doris Jones received.

So with that history, let's start -- or excuse me -- with that background, we'll start with the history of Bard's retrievable filters. 01:45PM

Back when Bard wanted -- next slide please -- wanted to first go to the market and get into the retrievable market it decided to do a small clinical trial to test the ability to retrieve the Recovery Filter. It wasn't a long-term study by no stretch of the imagination. It was about 60 days. And Dr. Asch, Murray Asch, will be here to talk to you about that clinical study. This is not a study for safety and effectiveness long term. It was only for retrievability. And one nice thing about going to Canada was that the laws, the rules for conducting this type of a study, you will hear from Dr. Murray Asch, was somewhat lax. It's easy to get through ethics committees. 01:46PM 01:46PM

The other important aspect of this study, this small 01:47PM

clinical trial to test retrievability, which averaged about 60 days, is that patients were closely monitored. They were under the eye and supervision of trained doctors, interventional radiologists. They weren't given the filters and then going off on their own. There were schedules on how they were going to come back so that the doctors in this study could determine whether these filters could be retrieved. 01:47PM

The patients in this study, they were watched closely, because essentially what they were undergoing was an experiment. Well, what was found during the course of the monitoring, Dr. Asch discovered that filters, the Recovery Filters, were not always remaining in position or intact. Now, why that's important is because to be effective, the filter needs to stay centered. The cap needs to stay centered in the vena cava, and the legs that spring out, you will hear from engineers, including a Dr. McMeeking, he will show you how the filter works after it's implanted. It goes through a tube and puts in a spring-like fashion, the legs spread across and around the inside wall of the IVC filter. 01:48PM 01:48PM

What Dr. Asch found is that the Recovery Filter wasn't staying in place. He found that it was migrating. There's two types you will hear about: Caudal migration is downward; cephalad or cranial migration is upwards toward the heart. And, of course, that was a concern because that means that the filter is not staying where it's supposed to stay. 01:49PM 01:49PM

The study also found that filters were tilting, not staying centered. And what you will hear is that when filters migrate and tilt, those can result in other problems like perforation, perforating through the vena cava wall. And you are going to hear something else that concerned Dr. Asch, is that filter legs look some like an umbrella without the canvas on it were fracturing and breaking and traveling. So that concerned Dr. Asch. 01:49PM

All in all, during the course of the study, Dr. Asch found that the Recovery Filter, which was in place in these patients in the study an average of 60 days, had tilted in five patients, migrated two times, fractured two times, perforated the vena cava once, and fractured two times. And this all happened in a relatively short time. And this all happened to patients, fortunately, who were under the watch and care of doctors. 01:50PM 01:50PM

Well -- next slide -- as you can imagine, this concerned Dr. Asch. And you will hear from him and he's going to tell you why. And while he found that the implanting of these filters, and he will explain how they go through, they go through various parts, jugulars or femoral arteries into the vena cava, all done percutaneously. And while they were, for the most part, retrievable, in other words, doctors could go in what you will hear is called percutaneous and pull them out, he saw these multiple failure modes, the ones we just saw. And 01:51PM 01:51PM

Dr. Asch told Bard, this filter is not ready for the market. He suggested that the Recovery Filter needs something long term. After all, what we'll find out is that Bard, to get this cleared on the market through the FDA, first made it a permanent filter, meaning it was supposed to, in theory, stay in place in a patient for a lifetime before they got clearance for it to be retrievable. 01:52PM

Well, Dr. Asch warned Bard that the Recovery was not ready for market. He indicated that these failure modes were concerning and something more had to be done. And Dr. Asch will tell you that he was basically assured by Bard that it wasn't going to go to the market. Well, in fact, you will hear that Bard proceeded anyway. 01:52PM

Now, here in the United States, there are two ways to get a medical device to the market. Bard chose to go through the 510(k) clearance process. That's what you are going to hear about. This is not approval. Let me repeat that. This is not an approval process. Under 510(k), the FDA relies on truthful -- truth, honesty, and accuracy from the medical device manufacturers. The FDA itself, you will hear, doesn't perform tests of its own. It doesn't even, or in this case, didn't even receive the device to inspect. 01:53PM 01:53PM

The FDA doesn't conduct any human clinical trials. It's an honor system. And it's an honor system that the FDA expects that there will be good corporate citizenship and that 01:54PM

medical device companies that choose that less-stringent method will do everything right, will do everything truthful, and will do everything accurate.

Essentially, clearance is a less rigorous process than what is called an approval process. Again, FDA doesn't test. They don't even do any verification of data. They rely that the data that's provided from the company that is seeking clearance, that that data is accurate. They rely on the company being truthful and accurate. 01:54PM

And what happens is -- next slide please -- a device company must give the FDA assurance that the device it is seeking clearance for went through this comparative route. That means that they can show that there is an existing device on the market and that the device they are seeking clearance for is the substantial equivalent. 01:54PM 01:55PM

And this is important. The 510(k) clearance is not official approval, nor a clearance by the FDA that the product is safe and effective. It's a clearance process. It just clears a device based upon a showing of substantial equivalence. And again -- next -- what's important from the FDA is that when someone from the device company signs a truth and accuracy statement that it is truthful and accurate and that no facts, material for review of the substantial equivalence of this device have been knowingly omitted. 01:56PM

So while dealing with the FDA, Bard made another 01:56PM

choice. It chose to go through the less stringent clearance way to get to the market and did not go through the more stringent approval process.

So what happened was that to gain FDA clearance to the market for the Recovery Filter, Bard advised the FDA that the Recovery Filter was substantially equivalent in terms of safety and efficacy to the predicate device, the Simon Nitinol, the filter who had a proven track record of safety, a permanent device. And you can see here by the arrows that we show, after the Recovery, based on the problems they, Bard didn't get out of the market. They didn't stop. They went to the G2. And from the G2 they went to a retrievable G2 and from the retrievable G2 they went to a G2X filter. And from that filter, to lose the baggage, they went to the Eclipse which, for all intents and purposes, was the G2. 01:56PM 01:57PM 01:57PM

Next slide. So Bard has to represent to the FDA and be truthful and accurate that the filter that it is seeking clearance for is substantially equivalent. But the evidence in this case is going to show that Bard misled the FDA and that the Recovery was never substantially equivalent to the Simon Nitinol Filter. And we believe the evidence will show you that the Recovery should have never been on the market in the first place. And because it doesn't get to the market, then there's no G2, there's no G2X, and there's no Eclipse. 01:58PM

Now how did Bard start to do this? Next slide, 01:59PM

please. You will learn from the evidence that Bard didn't fully, and didn't even study, the Environment of Use in any great detail and really didn't know much about the vena cava itself. But one thing Bard did know was that the vena cava, the vein itself, the largest vein, which is the highway to the heart, can distend up to 50 percent of its size. But Bard never chose to test for that dynamic. They didn't test beyond 28 millimeters of diameter of the vena cava. They didn't test anything beyond that diameter and didn't test for it expanding or distending, which as we will see, resulted in problems including migration. 01:59PM 02:00PM

In short, Bard did not understand the Environment For Use because it never tested for dynamic changes occurring in the vena cava, not just the vena cava distending by 50 percent but things from everyday movements, common movements, sneezing, coughing, things like that that can affect the diameter or dynamics of the vena cava. 02:00PM

What Bard did was Bard conducted bench testing. Now, the purpose of that testing should be to predict what will happen in the real world. But Bard used PVC pipe for the vena cava. It used sausage casing for the lining of the vena cava. It also conducted animal testing sheep migration in sheep to find out about how it resisted migration in sheep. And then Bard, as you know, went to Canada for a pilot study on implantation and retrievability. 02:00PM 02:01PM

But the evidence will show that Bard's testing had nothing to do with the real world of the vena cava and had nothing to do with the Environment of Use this device would be implanted in.

Next. When we talk about substantial equivalence, you are going to hear about a very important test. And this is called migration resistance. And what we have done to show how this test goes is you will look at a thermometer. And what happens is to find out if a filter in the IVC and the inferior vena cava can resist migration, you have to know something about the pressures. Otherwise, the filter will not resist and will migrate, as we learned the Recovery did, upward or can migrate downward. But the test, the IVC filter migration resistance standard really had no rhyme or reason. 02:01PM 02:02PM

You see, Bard knew the Simon Nitinol Filter was able to resist pressures -- the Simon Nitinol was able to resist pressures as high as 80 millimeters of mercury. The Recovery, though, couldn't. They found and established their own standards telling the FDA and others that the Recovery could resist 50 millimeters of mercury. Well, according to Bard, well, of course, if you can resist 80 like the Simon Nitinol, of course it could resist 50 millimeters. That's how they got to substantial equivalence. And Bard knew early after the Recovery that the filter has to be able to resist migration if it's going to do its job in catching clots and if it's going to 02:02PM 02:02PM 02:03PM

stay safe in patients.

What this test meant was that if a vena cava filter became occluded with a clot, the Simon Nitinol could resist the pressures caused by the blood flow in that vena cava up to 80 millimeters of mercury. And what they found was that the Recovery was nowhere close to that. 02:03PM

This meant that the Recovery would come loose much easier and would travel and not stay put much easier if it encountered any type of migration, if it could not resist migration in the vena cava. 02:04PM

Anyway Bard misled the FDA. It claimed that the 50 millimeters of mercury in the Recovery was substantially equivalent in safety and efficacy to the predicate device, the Simon Nitinol Filter, knowing full well that the Simon Nitinol Filter could resist greater pressures. 02:04PM

And Bard chose not to keep that information from the FDA but chose to keep that information to itself. It didn't share information like this with anybody; not its sales staff, not the medical profession, and certainly not end users, the people who these filters were put in. 02:05PM

But the evidence in this case will show you that Bard would learn quickly that that choice to use 50 millimeters of mercury would result in a number of problems, including migration, and they would find that migration and tilt would lead to other failures, including perforation and fracture. 02:05PM

Bard learned soon enough that these failures were related to each other, and that they could result in a cascade.

Now, just three years after they launched the G2 and just two months before the G2X was launched, Bard acknowledged something in its internal documents that they had been device focused; that they lacked a thorough understanding of dynamics of caval anatomy and that they had a limited understanding of user needs. They wrote that even though these devices were cleared that they had historical reactive evolution design mindset as evidenced by not stopping sales of Recovery when it was causing harm in people and going straight to the G2 which had a host of problems itself, including caudal migration. And they knew this two months before they launched the G2X, which was the predicate device for the Eclipse. 02:05PM 02:06PM

Bard acknowledged that the product complications that they were learning about and they were receiving and the reports that they were receiving about the problems that they had with the Recovery and the G2 was forcing them into a reactive designing mindset. Still, as the evidence will show, Bard chose to ignore the filter failures. The evidence will show that they misused an honor system, and that Bard never tested accurately the Environment of Use. 02:06PM 02:07PM

And the next slide shows you, this is what happens in a reactive design mindset. Bard cancelled plans for a long-term clinical test. They relied on data from the use they 02:07PM

were learning from use in the public. And they did this while they were developing the G2 and still selling the Recovery. They ignored and didn't do -- they ignored the cause of obvious Recovery failures and they continued with the reactive mindset to keep their place in the market. 02:08PM

And still, with all the adverse events that you will learn about that Bard was learning, they did not reevaluate the filter design as they had previously planned. They continued a reactive design mindset. And even in December 9 of 2003, Bard's own internal engineers wanted to re-evaluate. They 02:08PM wanted documentation to explain this 50 millimeter of mercury pressure standard that was created by Bard, the one that the engineers were saying was not substantially equivalent to the predicate device, the Simon Nitinol Filter.

So when we talk about aggressive marketing, that's not 02:09PM made up. That's a fact. This is a Bard document. And we believe the evidence will show that this is how Bard dealt with untested failure modes. Bard bought into this, and this is in their documents, that users can be swayed by aggressive marketing in spite of negative clinical experience. And that's 02:09PM exactly what the evidence will show, that in confronted with negative clinical experience, Bard, through its sales force, through its marketing department, went about and used aggressive marketing.

And the evidence will show that the way the Bard 02:10PM

Recovery, the G2, and eventually the Eclipse got to the market was because marketing, aggressive marketing, won over science. Because Bard made choices and choices not to do the appropriate test, choices not to be honest with the FDA about the 50 millimeters of mercury. 02:10PM

Well, consistent with its reactive design mindset, Bard started plans to modify the Recovery. The Recovery you will find was causing all sorts of problems. It was migrating up. It was causing all sorts of serious injuries in patients. And internally, Bard called the new G2 the Modified Recovery. 02:11PM But something happened when they were looking at the next generation to hold their market share. You see, the G2 was going to have to be cleared as a permanent device first.

Well, knowing that it had issues with the Recovery, knowing that it was in this reactive design mindset, knowing, 02:11PM though, that it could rely on aggressive marketing, Bard had a problem. Because you see when they went to compare the G2 with the Simon Nitinol Filter, the one with the proven safety track record, they found out that they had a problem much similar to the Recovery Filter; that the G2, like the Recovery, could only 02:11PM resist maybe 50 millimeters of mercury. That the G2 could not meet the standard set by the Simon Nitinol Filter, the permanent filter with the proven track record at 80 millimeters of mercury.

So what Bard did was they had to deal with that 02:12PM

problem. And meanwhile, problems are mounting. It was becoming clear to Bard that the bench standard that they did of the 50 millimeter of mercury in the Recovery was causing problems. Bard's own quality engineer saw that the injuries that were being reported to Bard were significant and that there was a major difference between the Recovery Filter and the Simon Nitinol Filter. In fact, the injuries reported that Bard's were so much higher in the Recovery Filter, but Bard still made a choice and they kept the Recovery on the market knowing that Natalie Wong, the quality engineer, had said that at a 95 percent confidence, there is a significant difference between the Recovery and the Simon Nitinol Filter. You will hear from Natalie Wong and that testimony will come to you via videotape deposition, which is a way we're going to present some of the evidence because people live all over the country and cannot come to court. 02:12PM 02:13PM 02:13PM

Knowing that the G2 had the same flaw as the Recovery, Bard had essentially changed the goal post. And by doing that, Bard had to make a choice and the choice was that the Simon Nitinol Filter could no longer be the predicate. If they were going to get the G2 in a reactive mindset and keep their share out there in the market knowing that they hadn't done any type of long-term testing, they had to do something to show substantial equivalence. So what Bard did was they changed it, and they changed the Recovery, the Simon Nitinol, as a 02:14PM 02:14PM

predicate to the Recovery. And rather than reporting the failure that the G2, its filters had experienced during the course of testing, Bard just simply changed the standard and changed the standard itself to this internal standard that 50 millimeters of mercury in migration resistance testing was safe and so, therefore, the G2 was the substantial equivalent of the Recovery. And the Recovery Filter became the predicate device for the G2. 02:14PM

And despite knowing the flaws, the deficiencies that the G2 had, after all, it was the generation from the original Recovery. Nothing changed too much in that family of filters. But instead of stopping, reevaluating, opting for accurate testing, telling the medical community, telling the FDA that the G2 was not going to be any better in terms of migration resistance, Bard relied on its old time tested strategy, aggressive marketing. 02:15PM 02:15PM

Now, you heard about the Murray Asch study. And I believe the defense will talk to you about an Everest study. The Everest study was a study involving G2 and just a short-term study for purposes of retrievability. It did not evaluate the long term safety of the G2, which was originally cleared as a permanent device, a device represented that would stay in place in patients. In fact, Bard's sales brochures promised that the G2 was going to take strength and stability to a new level. You see, Bard was concerned. Doctors were 02:16PM 02:16PM

losing confidence. They had bad experiences with the Recovery but they had a very good sales force. The sales force, you will hear, is the face of Bard. That's how they get their devices out there. The sales force develops relationships with doctors, and doctors rely on the sales force, as you will hear, for truthful and accurate information. Credibility is everything in those relationships. And you will hear that Bard knew that, and knew that well. 02:17PM

They knew it so well, that when they knew about some of the deepest, darkest problems they had with filters, they wouldn't share that with the sales force because they didn't want to put their sales force in a position where they might have to be truthful with doctors. They said about the G2 that it increased migration resistance. It improved centering and that it had enhanced fracture resistance and Bard would find out sooner than later that it didn't. 02:17PM 02:17PM

As a matter of fact -- next slide please -- by December 23rd, 2005, David Ciavarella, who was their medical director, he became concerned about what he was learning about the G2. He wanted to look at the G2 complaints. He, himself, saw problems that the G2 was presenting with caudal migration, tilting, perforation, misdeployment, and it kind of sounds familiar because these are the same things that Dr. Asch was saying. 02:18PM

Well, Dr. Ciavarella was concerned. And he had said 02:18PM

in this e-mail on December 23rd, 2005, that the biggest worst-case consequence of migrations that they were seeing with the G2, caudal migrations, downward migrations, is that in the majority of the cases the migration was accompanied by tilt. And what you will hear from the evidence is that tilt and migration can lead to other complications like perforation and fracture. And Bard was becoming more and more aware of that, that tilting itself and migration were serious problems because they could lead to what's called a cascade. 02:19PM

And yet, the evidence will show, knowing about caudal migration and the numbers that Bard was receiving, knowing that they had concerns that these failure modalities were related to others, Bard said nothing. Nothing to the medical community, nothing to the end users. Dr. Ciavarella brought up a point, he said, well, if it's tilting, how is that going to address efficacy in clot trapping? Because after all, when we saw the filter before it has to be centered because it would catch a clot just like think of a web from an umbrella. If it was tilting, Dr. Ciavarella's concern was how can that effectively trap a clot and prevent it? 02:19PM 02:20PM

But Dr. Ciavarella also felt something very, very important, and he stated it in an e-mail. Because he knew, just like Bard knew, that they had a filter. They had a filter with a proven track record of safety, and that was the Simon Nitinol Filter. And the medical director himself wondered out 02:20PM

loud in an e-mail, with the Simon Nitinol Filter still on the market for a permanent filter, why wouldn't doctors rather use that. After all, the Simon Nitinol Filter had virtually no complaints according to Bard's medical director.

Well, Bard learned soon enough about just how bad caudal migration was in the G2, so much so that Natalie Wong did her studies, and she found it to be an unacceptable risk per failure mode and effects analysis, and that had to do with the numbers of G2 migrations that Bard was receiving, just complaints they were receiving. Yet Bard didn't share this information with people that needed to know. They didn't tell doctors. They didn't tell the public and they didn't tell the people who were going to receive these filters. But right there inside Bard, their own quality engineer Natalie Wong found the caudal migrations by G2 was unacceptable, unacceptable risk. 02:21PM 02:21PM 02:22PM

You are going to hear from a Bard employee, Janet Hudnall, who was a person in Bard's marketing, somewhat the architect of marketing launches for the Recovery and the G2. And this is an e-mail exchange between Janet Hudnall and another sales representative, Jason Greer. And when you hear from Janet Hudnall, and you will hear from her in a video deposition, listen to her because she's going to say something else very, very insightful, something that Bard knew, something that she knew. Her and Jason Greer were lamenting over the two 02:22PM 02:23PM

years prior to this e-mail in 2006 over the problems and how she held it together with Scotch tape, smoke, mirrors, crying, et cetera. Well, that was the problems with the Recovery and the G2. And you can imagine that if a company is going to make a choice and use aggressive marketing over science, over 02:23PM studies, well, that's a big chore when you have filters migrating up and down and they are tilting and they are fracturing and they are injuring patient after patient. It's kind of tough to keep your market share if you make a choice to aggressively market. 02:24PM

Well, Jason Greer and Janet Hudnall were proud of the way she handled that. But Janet Hudnall is also going to say something very insightful. She has stated that there is absolutely -- there is no way to know whether filters have ever stopped a clot. And this comes from the marketing person. In 02:24PM other words, the aggressive marketing people were even questioning, while they are setting aside all the dangers, setting aside all the risk, whether the filters they were putting out, they were pushing hard, were even doing what they said they would do. 02:24PM

Well, what it means in Bard when you have an unacceptable risk, it means that you have a failure that can contribute to the death, severe injury, permanent significant disability, or severe occupational illness. And this was what was found about the G2. And keep in mind, the G2 went to the 02:25PM

G2X. The only change was a hook. And the G2X was the predicate for the Eclipse. And just back in 2006, a quality engineer in Bard was finding that caudal migrations in the G2 was an unacceptable and a dangerous, serious, risk.

The Eclipse was launched in January 2010, and the evidence will show you that the Eclipse is essentially the G2X. It has the hook. They electropolished the legs. And what that means, well, the evidence will tell you that despite what Bard tried to suggest that it might help with fracture resistance, making the filter more resistant to fracturing the legs, that engineers involved in the development didn't think so. 02:25PM 02:26PM

Really the reason the Eclipse was launched was because of aggressive marketing and the need to keep that market share. The name was chosen to break the baggage, the baggage that Bard had experienced from the complication of adverse events, the problems and injuries it had from the predicate devices, the Recovery and the G2. And so in its endeavor to aggressively market, the Eclipse came and was cleared. 02:26PM

And what Bard did was it got to their sales force and really pushed this whole concept of electropolishing. This is Chris Smith. He is a sales representative, and he testified, and you will hear him by videotape deposition here, video recorded deposition, that they were promoting both the G2 and Eclipse as being resistant to fracture, and that the sales force, like the medical community, like the patients, expected 02:27PM 02:27PM

that Bard would have taken steps to improve the G2 and improve the Eclipse in terms of fracture resistance. But the evidence will show otherwise.

In fact, there will be evidence and testimony from Ms. Raji-Kubba, another person who works at Bard, and she was involved in the development of the Eclipse Filter, the filter that Doris Jones received. And she admitted in deposition that the question was: Okay, so you didn't expect to reduce the increase, the migration resistance of the filter? Her answer was specifically, no. And you didn't expect to reduce the fracture rate of the filter? And she said not -- not the electropolishing itself. Yet, as you can see, Bard was representing that electropolishing would improve fatigue resistance, which meant would improve stability, which meant Bard was representing that this filter had improvement in being resistant to limbs fracturing. 02:28PM 02:28PM 02:29PM

Well, as the evidence has shown, or will show, excuse me, Doris Jones received the Eclipse Filter and she received it in 2010. Now I want to talk a moment about Doris.

She is married to Alfred Jones. She is a mother. She has her daughters, Shanice and Sharese. They live in Savannah, Georgia. Doris is a proud grandmother. She has three grandchildren; Chastity, Zi'Yari, and Monae. 02:29PM

And here's what Doris has done with her life as a mother and a grandmother. The evidence will show you that 02:29PM

Doris is intent on having her daughters have a better life than hers. And what she provides her daughters every day is peace of mind because, see, Shanice and Sharese can go do their jobs every day knowing their babies are in the best of hands, that their babies are going to be safe and with a loving person, the same person who raised them. And that's what Doris does. You will hear from her. That's what she is proud of. That's what her goal is, and that is what she is intent on doing. 02:30PM

Now, in August 2010, Doris went to Memorial University Medical Center in Savannah, Georgia. She had symptoms associated with gastrointestinal bleeding. She was also diagnosed with an acute deep vein thrombosis. Dr. Anthony Avino performed placement of a Bard Eclipse Filter, and you will hear testimony that it was intended to be permanently in place. 02:30PM 02:31PM

Doris Jones eventually returned, and a CT revealed that the Eclipse Filter in her in 2015 had fractured. An arm of the filter had fractured. It had migrated, it embolized, embolized meaning it traveled through the circulatory system in the bloodstream. You will hear from Dr. Meuhreke and Dr. Hurst, they will explain how it happened, how the pathway of this fragment went. As a matter of fact, we've got three quick animations of that we can show you right now. 02:31PM

So what you are looking at is the anatomy. There's the IVC filter. This shows how the filter moves within the 02:32PM

vena cava. The vena cava, you will find, is a vein that expands and contracts, and the filter fractured.

Next animation. Again, if you are looking at the screen, we're showing you the fracture embolization. The fragment breaks, and this is how it eventually gets to the pulmonary artery where it's embedded. It goes through the heart. And our doctors will tell you about how the pathway to get to where it is, the pathway that strut had to take. And it eventually finds itself in Doris's pulmonary artery. 02:32PM

Now, she went in and she had the filter removed, but the doctor that removed the filter felt that it was too dangerous to go after the strut in her pulmonary artery. Let's show the retrieval. This is how doctors will tell you in this case how filters are retrieved. And Doris went and underwent this procedure to have the filter removed. But that strut remains in her. And that strut remains in her to this day. And she is going to tell you about it. She's stoic. She's brave. She's courageous. What she doesn't want is she doesn't want her daughters or the grand babies, or her husband, for that matter, to know her fear. But her fear is what could happen? What can happen when you have a foreign object embedded in your pulmonary artery? She fears that she may be caring for the grand babies, and something incapacitating has happened. 02:33PM 02:34PM 02:35PM

But what the evidence will show is from Bard's 02:35PM

choices, the harmful choices that Bard has made, that now they have imposed a choice on Doris. And that choice is this: Leave that fragment, not knowing what could happen, or go through a risky surgery.

Now, Bard is going to claim in this case that Doris doesn't have symptoms so she must not be hurt. But what the evidence will show is that Bard in its internal documents is very aware that migrations of fragments to the heart or lung present serious clinical consequences. You see, that's what they know up there. But in this courtroom we anticipate they are going to suggest that Doris doesn't have symptoms. So for some reason, she's not hurt. And Doris is here today because of Bard's bad choices. 02:36PM 02:36PM

MR. NORTH: Your Honor, I'm objecting. That's argumentative. 02:37PM

THE COURT: Let's stick to the facts, Mr. O'Connor, please.

MR. O'CONNOR: Sure.

Documents that Bard has produced say and admit that they knew little about long term clinical performance of its filters. Physicians tell Bard that they are more comfortable with a small PE, that's what they said in a focus group, that is asymptomatic than a fracture. And documents will show that Bard knows that its asymptomatic events probably occur at a much higher rate because they are underreported. 02:37PM 02:37PM

Now, what we anticipate is that Bard is going to come here and they are going to present evidence. They are going to present evidence about their failure rates and try to show that the failure rates are not that significant. Keep in mind, though, that Bard, the reporting system in the United States is voluntary. Doctors, hospitals, and patients in the health care community are not required to report injuries associated with medical devices to Bard or the FDA. Bard, though, is required to report injuries that it becomes aware of. 02:38PM

Now, there will be evidence, and this comes from Dr. Ciavarella, who you will hear by video recording, and he will testify about the problems associated with reporting. And he will testify, and has testified, that the reporting, only probably 1 to 5 percent of what's actually going on out there is being reported. 02:38PM 02:39PM

So in the end, we think that while the evidence will show you medical devices implanted inside bodies do carry risks. But when a company knows that its new medical device increases a risk and sells it anyway, that causes harm. And while you will hear evidence that IVC filters carry risk, we believe the evidence will show that Bard knew that its IVC filters had increased risks of harm but they sold them anyway. And by making that choice, Doris Jones has a fracture that embolized to her pulmonary artery and remains there. 02:39PM

So, in summary, the evidence, we believe, will show 02:40PM

this: Bard wanted to sell its IVC filters. What research it did beginning with Dr. Murray Asch showed that there were potential problems. Bard's own testing showed that its filters carried increased risk and, in fact, they weren't better than the predicates. 02:40PM

What a company should do is not sell it. And that way nobody can be harmed. Bard made a choice, despite what the research told it, to continue to market, continue aggressive marketing, and that's how people like -- that's how Doris Jones got hurt. And that's why we're here. 02:41PM

Now, we believe in this case that we will meet our burden of proof, that at the end we believe that the evidence will show that Bard's choices that you will hear about in this case, choices to ignore science, choices to ignore the need for long term clinical studies, choices to ignore the need for 02:41PM accurate testing, those choices resulted in dangerous filters which cause harm.

We believe that the evidence will show that Bard didn't warn the medical community or end users of what it was becoming aware of on a regular basis, that its filters were 02:42PM causing harm. And we believe that the evidence will show that Bard engaged willfully and made choices that it knew created risk of harm to patients like Doris.

At the end of this case, we're going to ask you for a verdict, a verdict that compensates Doris for her injuries and 02:42PM

damages and a verdict that will mean something in this case.

I want to thank you for your time. Thank you.

Thank you, Your Honor.

THE COURT: Thanks, Mr. O'Connor.

Ladies and Gentlemen, we are going to take an afternoon break. We'll take a 15-minute break and begin again at just before 3:00. Please remember not to discuss the case and we will excuse the jury at this time. 02:42PM

(Jury out at 2:43 p.m.)

THE COURT: Counsel, is there an issue I need to address or are we resolved? 02:43PM

MR. CLARK: Your Honor, we just have one. It's with respect to -- my colleague was going to argue it -- but with respect to one of the exhibits, Exhibit 1035, I believe, Bard had an objection. I think the remaining -- is that not the case? 02:43PM

MS. HELM: We do have an objection to Exhibit 1035, Your Honor. The basis of our objection is that they are attempting to tender it with the deposition of Jason Greer. And Exhibit 1035 is not an exhibit to his deposition. So it's a document that they are seeking to tender that the witness didn't testify about and it's not a part of his deposition. 02:44PM

THE COURT: Are you saying they are just going to offer it into evidence?

MS. HELM: That's my understanding, that they told me 02:44PM

they just wanted to offer it in evidence.

MR. COMBS: That's correct. We're moving it into evidence under Rule 104. The only objection they offered is a relevance objection. It's a fracture report from 2004. It's clearly relevant on a number of issues. 02:44PM

THE COURT: It doesn't have anything to do with what's going to be played in the deposition, is that right?

MR. COMBS: That's true. It's not referenced in the deposition.

THE COURT: Let's talk about it at the end of the day after the jury has been excused. Thank you. 02:44PM

(Recess from 2:44 p.m. until 3:02 p.m.)

THE COURT: Mr. North, you may proceed with your opening statement.

MR. NORTH: May it please the Court, Ladies and Gentlemen of the Jury, good afternoon. It is my honor and it's my privilege to be here today, and it is for my colleagues to be here to represent the men and women of C.R. Bard and Bard Peripheral Vascular. 03:02PM

We are proud to do so, and it is my task today to present to you a summary of what we think the evidence is going to show in the next three weeks, to show you what we believe is the other side of the story from what you just heard. 03:02PM

And we do believe that you will hear, over the course of this three weeks, a completely different side of the story. 03:03PM

If Bard believed what we just heard from Mr. O'Connor, we would not be here today if the evidence showed that this case long ago would have resolved. But we believe that the story and the evidence is different from what you just heard. And then once you hear that evidence, and once you hear the whole story, that you will determine that Bard stands in this courtroom wrongfully accused. 03:03PM

The evidence is going to demonstrate one central key issue for your consideration, and that is an issue that we hear about in the medical field all of the time. We heard about that issue. Some people discussed it this morning. It's a risk benefit analysis. And that's the central issue that the evidence is going to be presented on day in and day out. 03:04PM

And it ultimately, after you hear all that evidence, what you are going to have to determine is whether the benefits of the Eclipse Inferior Vena Cava Filter outweighed the risks, and there are risks associated with that device. And we believe that the evidence is going to show you that these filters have a tremendous benefit. They save human lives. I can't imagine what greater benefit there could be. And yes, while there are risks, we believe that the evidence is going to show you and demonstrate that the lifesaving potential of the Eclipse Filter outweighs the risk of complications that come with the device. 03:04PM

Over the course of the next few minutes I'm going to 03:05PM

be presenting to you what we believe the other side of the story is, what we believe the evidence will show, you warts and all, will indicate the entire whole story. The purpose of opening statement here is to provide you a road map, a summary of where we believe the evidence is going to go, where it's going to take us as we listen to the witnesses, as we review the documents, and at the end of the day when we hear the final arguments. 03:05PM

First, today, as a part of this road map, I would like to make a brief stop and tell you about my clients C.R. Bard and Bard Peripheral Vascular. They are not just names. They are just not monolithic corporations. They are entities with a history and a function and a community purpose. 03:05PM

After talking about Bard and Bard Peripheral, I'd like to tell you more about the device; not the Recovery Filter which we heard about so much this afternoon, not the G2 Filter which we heard so much about this afternoon, but evidence about the Eclipse Filter, the fourth generation retrievable filter developed by Bard and the filter that was implanted in Ms. Jones. 03:06PM

And then I would like to talk to you about Ms. Jones, about her medical course, the difficulty she's had and why she needed this filter and why she needed this filter to potentially save her life. And then I lastly want to talk to you about the plaintiff's burden. Because at the end of the 03:06PM

day I believe the Court will instruct you that it is the plaintiff's burden of proof to prove, by a preponderance of the evidence, her case. And I would like to talk about the elements that she needs to prove in order to recover and what we believe the evidence will show as to those elements. 03:07PM

But first, as I indicated, let's talk about Bard. Let me tell you a little bit more about the two companies I have the honor of representing.

C.R. Bard was founded more than a hundred years ago by a physician and designer, or inventor, by the name of Charles Russell Bard. 03:07PM He began research on how to treat urinary discomfort. He was the inventor of the Foley catheter, a device that is still the most widely used urinary catheter and widely sold urinary catheter in America today.

But Bard has expanded beyond, over the years, just 03:08PM catheters and urinary treatment products. Bard is located in Murray Hill, New Jersey. It manufactures and develops many different types of medical devices. It makes vascular devices, urological devices, oncology devices, surgical specialty devices. And then there's Bard Peripheral Vascular which is a 03:08PM division of Bard. It's located just down the road in Tempe. And there, that company, that division, specializes in two types of products: Oncology products and vascular products. It makes stents. It makes filters. It makes many different products to treat vascular diseases. And it is a major 03:08PM

developer and producer of biopsy products making some of the most widely sold and utilized biopsy, cancer biopsy products used in hospitals throughout this country.

But Bard is not just a faceless corporation. It's made up of men and women that go to work in New Jersey and Tempe every day, that visit hospitals, that talk to doctors, and that attempt and strive to produce medical devices consistent with the core values that the company has developed. 03:09PM

Again, it's not just a faceless corporation. It's made up of biomedical engineers, regulatory specialists, quality assurance specialists, in-house physicians, and many other dedicated professionals. And these are men and women that you are going to see, virtually all, if not all of them, during the course of this trial, men and women that do work or have worked with Bard or Bard Peripheral in the development of these filters, in discussions with the FDA about these filters. And I believe the evidence is going to show you the pride and care that they have applied in developing and selling these lifesaving devices. 03:09PM 03:10PM

Now, let's talk about the device, the Eclipse Filter. But before you can really, I think, at least before I could really appreciate what this device is, how it works, and what it does, it helped me to learn more about the diseased state that it is intended to treat. 03:10PM

DVT, or deep vein thrombosis, and pulmonary embolism, 03:10PM

I think we have all heard of them. Most of us have friends and relatives that have suffered from them. They are a pervasive and life threatening medical condition that unfortunately affects too many of us and too many of the people we love. Deep vein thrombosis are blood clots develop in the legs, the lower extremities. We often hear about deep vein thrombosis or DVT from people who are riding on airplanes for long distances. We have all been told or read if you are riding on the airplane, get up and walk around, drink lots of water. It's to avoid that condition, deep vein thrombosis. It's not just airplane flights. There are many other things and health conditions that can cause that. 03:11PM 03:11PM

Deep vein thrombosis, while usually treatable, can quickly become fatal if it develops into pulmonary embolism. And that's when the blood clots in the leg break free and travel up and clog either the heart or the lungs, this massive clot, and it kills people. It kills people in this country every day. 03:11PM

Each year due to DVT, approximately two million of our fellow citizens are affected. Up to 600,000 people a year are hospitalized. And doctors and experts estimate that as many as 2- to 300,000 people die from pulmonary emboli caused by deep vein thrombosis every year. 33 percent, one-third of all people who have had an incident of DVT are going to have a recurrent DVT in the future. 03:12PM 03:12PM

And I have always been shocked by this particular statistic: DVT-related pulmonary embolism is the leading cause of preventable hospital deaths in United States hospitals. It is a serious issue, an issue that the medical community and the government recognizes. 03:13PM

In 2008, the United States Surgeon General issued a call to arms because they were so alarmed about the deaths and the problem of pulmonary embolism in our country. They noted the seriousness of the disease. They noted that it causes more deaths in this country each year than breast cancer, than AIDS, 03:13PM or even motor vehicle accidents. And they said that the status quo is unacceptable. And they also recognized that inferior vena cava filters, like the Eclipse Filter, are an appropriate method of treating this disease in a number of patients.

And it is to treat that disease, that life-threatening 03:13PM disease, that the men and women of Bard developed retrievable inferior vena cava filters, including fourth generation filter, the Eclipse.

Now, as Mr. O'Connor indicated, the inferior vena cava is the largest vein in the body. It's that big blue vein that 03:14PM comes up the center. The veins from your legs feed into it, merge, and meet into the inferior vena cava and it returns the blood from the lower legs up to the heart. The filter is implanted, and you can see approximately where it is implanted, not far from the kidneys. It's implanted in patients to break 03:14PM

up the clot. It's sort of like a strainer when you are cooking something and you are pouring a liquid that has some particle in it to try to strain the particle, to keep the clots from coming to the heart.

I'd like to show you an animation that shows a filter breaking up a clot so you can see how it's supposed to work. You see the clot. The idea is the filter hits it, and it breaks apart, just like with a strainer. 03:15PM

Now, let me tell you a little bit about Bard's history with inferior vena cava filters. The first filter that the company sold was called the Simon Nitinol Filter. And for years, that filter was developed and manufactured by a different company called NMT, Nitinol Medical Technology. But Bard was the distributor for that filter. 03:15PM

It was very much unlike the Eclipse Filter at issue in this case because it was a permanent filter. Once you put it in somebody, you could not take it out. And for that reason, most of the time physicians would just put these permanent filters in terminally ill patients that weren't going to be living much longer or the elderly, who didn't have many years to live. You would not put it in a young trauma victim, let's say a teenager in a motor vehicle accident that had broken bones and was going to be laid up in the hospital. Those people are at very high risk, even at the young age, because they can't move and mobilize and have a high risk of DVT or 03:16PM 03:16PM

pulmonary embolism. But doctors didn't want to put permanent filters in those people. And so they were deprived of a very important treatment option for those patients.

Bard acquired the right to the SNF, the Simon Nitinol, and to the Recovery Filter which was still being developed and had not been cleared by the FDA for sale in 2001. In 2003, Bard introduced the Recovery Filter, and it was initially cleared by the FDA to be used as a permanent filter. It eventually was cleared by the FDA to be used as a retrievable filter. And we'll talk a little bit more about that in a minute. 03:17PM

But Bard is constantly evolving, constantly innovating, and very quickly began work as it assessed its experience with its first retrievable filter, the Recovery Filter, began work on the G2 filter, the second generation. It began work on that filter in 2004. And the FDA cleared the G2 Filter as a permanent filter in August of 2005. 03:17PM

From August of 2005 to October of 2007, Bard conducted a clinical study concerning the G2 Filter. It was a two plus year study involving 100 patients, tracking those patients, cataloging their experience, their complications, and reporting the data on a frequent periodic basis to the FDA. 03:18PM

In January of 2008, the FDA cleared the G2 to be used as a retrievable filter. And then after that, Bard developed the G2X Filter, the third generation filter which took the G2 03:18PM

Filter and put the hook on the top. And then in 2009, Bard began developing its fourth generation filter, the Eclipse, the one that is at issue in this case. And in January of 2010, the FDA cleared the Eclipse Filter as a retrievable filter.

Now, what was so special, or what was so unique about the retrievable filters developed by Bard? The only retrievable filters before Bard introduced the Recovery Filter that existed could be left in the body for no more than 10 to 14 days before they had to be removed. So if you had a patient, lets go back to the example of the trauma patient who is going to have multiple surgeries for broken bones and be laid up in the hospital for a month or so, you couldn't use one of these filters. And it was a predicament for physicians because these filters are used in patients when for whatever reason they cannot be on blood thinners like Coumadin. We heard a lot of discussion about that this morning. Coumadin or other drugs called anticoagulants are the first line of defense for doctors for pulmonary emboli or deep vein thrombosis. But when a patient has a high risk of bleeding, doctors have to take those patients off blood thinners. You cannot be on a blood thinner and go into surgery. So they have to have another method to protect those people of the risk of clots. And until the development of Bard's Recovery Filter and its retrievable filters, they really didn't have that option for any patient that needed a filter more than 10 to 14 days. It

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was either a permanent filter or no other option.

For Bard's retrievable filters, including the Eclipse Filter, however, there was no limitation on what's called the in dwell time, how long that filter could be kept in the body before it was retrieved. 03:21PM

There is data, there are studies, that show Bard retrievable filters, including the Eclipse Filter, being retrieved months after they are implanted, years after they are implanted. There are some doctors that specialize in these filters that say they can retrieve these filters many years 03:21PM after they have been implanted. And that was a major breakthrough for the medical community. These filters could either be left there permanently or the doctor had the choice to retrieve them when they were no longer needed. And again, that was especially beneficial for patients with only a 03:21PM temporary need for the filter.

Now, Bard's filters are made of a very unique product called Nitinol. Nitinol is a substance. It's a type of metal that was developed by the United States Navy. In fact, its name is an acronym for Nickel Titanium Naval Ordinance 03:22PM Laboratory where it was developed. It was developed in 1962. And what makes it unique is that it has what is called shape memory. Once you forge a device or a product out of this substance, Nitinol, it remembers its shape.

So, for example, the filter is manufactured by Bard. 03:22PM

It is then compressed. You saw that a few moments ago when it was being retrieved in their animation and I will show you another one in a minute. But it's compressed. And then when it is released from the catheter in the human body, it remembers the shape that it was forged in and springs out to that shape. And that's what it means by shape memory. And the temperature is what helps that process to occur. 03:23PM

Here is an animation of a filter placement. There are two ways to implant these filters. One is through the femoral vein, which is the vein, of course, right in the groin, and one is through the jugular vein in the neck. Both are done with a small incision. It's called a percutaneous procedure as opposed to any invasive surgery. It's a small incision. The catheter is placed, run up through the inferior vena cava, and then the filter is released. 03:23PM

Here's what it looks like. You can see the guidewire coming up. This is coming from the femoral vein, or from the groin. Then comes the catheter, and the filter has been compressed inside the catheter. It is then released. The filter remembers its shape and springs in to fill the IVC. 03:24PM

These procedures, on average, take about 25 minutes, often done under no regular anesthesia, just local anesthesia, done in a clinic or a specialized room in a hospital, usually done on an outpatient basis. It is a very simple procedure as is the filter retrieval. If a doctor is ready to retrieve the 03:25PM

filter, they then do something very similar. But this time they go through the jugular vein with a special device in a catheter that collapses the filter. And here's an animation that depicts that. Collapsing it back, pulling it into the catheter, and removing the catheter. 03:25PM

Again, this procedure is performed simply with an incision often under local anesthesia. It is performed percutaneously and a very brief procedure, usually. Ms. Jones in this particular instance, when the filter was retrieved, the medical notes and chart indicate that the procedure took 34 minutes. 03:26PM

Much of the plaintiff's evidence which you just heard described in this case concerned the first generation filter, which was sold between 2003 and 2005, the Recovery Filter. But this case is not about the Recovery Filter. The Recovery Filter was not implanted in Ms. Jones. 03:26PM

The G2 was developed in 2005 with the express purpose of improving the Recovery Filter to try to improve its resistance to migration, to improve its resistance to fracture. And you will hear about the design changes that were made to address much of the problems or issues that Mr. O'Connor just described. The FDA was alerted and advised of all these design changes. 03:27PM

And you will hear how the G2 was designed differently from the Recovery Filter, specifically to make it more 03:27PM

resistant to migration and fracture. But then again, this case is not about the Recovery Filter. And it's not even about the G2 Filter. Because the G2 was not implanted in Ms. Jones.

This case is about the fourth generation filter, the Eclipse. And what made the Eclipse different is that it was electropolished, a special treatment performed on the wire that makes up the filter. Again, Bard stopped selling the Recovery Filter, which you heard so much about in 2005. It was five years later, three generations of filter later, that Ms. Jones received her device. Bard had improved the G2 to make it better, more complication free, than the Recovery Filter, and then went further and designed the Eclipse Filter to electropolish it with the goal of further improving fracture resistance. 03:27PM 03:28PM

You will hear material specialists and engineers from the company and outside experts talk to you about what electropolishing does. It smooths out the surface of the wire and it reduces or eliminates surface imperfections. And Ladies and Gentlemen, I submit to you that some of the most important evidence you are going to hear during the course of this case is how that process and how that work to improve these filters, how it succeeded. 03:28PM 03:29PM

And the best evidence of that that you will hear are going to be the reports to Bard of complications. And those reports are going to show that the reports of complications 03:29PM

from the G2 Filter were much better than the reports for the Recovery Filter. And the reports for the Eclipse Filter were better than those of the G2, that the design changes and improvements in evolution was making a difference.

And this is based on all the reports of complication received from Bard from whatever source, whether it's the FDA, whether it's hospitals, doctors, whether it's studies published in the medical literature. From whatever source it comes, Bard collects that data. And you look at that data, and it demonstrates that 99.83 percent of Eclipse filters sold had no reports of fractures, which Ms. Jones had occur with her filter. 03:29PM 03:30PM

This case is about the data regarding the Eclipse Filter. That was the filter that was implanted in Ms. Jones. And let's talk a moment about Ms. Jones. 03:30PM

And I want to tell you also one thing that there will be no dispute about in the evidence at all. And that's the fact that everyone, you, as members of the jury, us as human beings, have sympathy for Ms. Jones. She has had a difficult medical course, unrelated to the filter even, which you will hear about. She has had two episodes of deep vein thrombosis. She needed the filter. She has had a difficult course. And we are not here to malign her. The evidence is not going to create an issue about Ms. Jones because she's a human being and we're all human beings. And we all have sympathy for her. 03:31PM 03:31PM

She did have serious medical issues, though. In October of 2006, she was hospitalized for a gastrointestinal, a stomach-area bleed, and she has a history of bleeding issues, gastric bleeding issues. She had to have surgery, gastric surgery, in 2006. And during that time while she was in the hospital, she was diagnosed for the first time with a deep vein thrombosis. In April of 2009, three years later, she was hospitalized with abdominal pain which was attributed by her doctors to, in part, to anemia, and she had to have additional gastric surgery. 03:32PM

In 2010, she was hospitalized with another GI bleed. She had fatigue and severe anemia at that time. At this point she still did not have a filter, but she was complaining of fatigue.

She was diagnosed with another, her second incident of deep vein thrombosis. And here's where the filter comes into play. She had just had her second episode of deep vein thrombosis. But because of her GI bleed, she needed surgery. And the doctors couldn't conduct surgery given the -- with her own anticoagulant because she had previously been prescribed, I believe it was, Coumadin. They had to make sure she was not on a blood thinner or else they couldn't perform surgery. And that's when their option became to implant an IVC filter, which the doctor did without any incident, without any complications. And she therefore, two days later, was able to undergo her 03:33PM

gastric surgery.

In 2010 -- I mean 12, two years later, she was hospitalized with chest pain. Chest x-rays were performed, and this is important, two years after the filter was implanted, it's still there, and there was no evidence on the x-rays of any fracture with the filter. 03:34PM

Again, in 2013, she was hospitalized. She had another chest X-ray. And at this point, three years after the implant, she had no evidence of filter fracture. And then in 2015, she was hospitalized again, and a chest X-ray then showed one strut from the filter had fractured and had traveled through her bloodstream and was then stationary in a pulmonary artery, a larger artery in the lung where it was stationary. 03:34PM

So her doctors assessed the situation. They removed the filter, which was still in place, and they removed it in that 34-minute procedure I described a few minutes ago. And the radiologist who did that procedure decided to leave the strut in her pulmonary artery. And this is important, because that radiologist determined that that strut was in a safe location. 03:35PM 03:35PM

And that's hard for us as lay people to understand, but you are going to hear doctors talk about that. It sounds scary to have a metal strut in your heart -- I mean not your heart, I'm sorry, your pulmonary artery. But what happens in the vast majority of cases is that the foreign object becomes 03:35PM

endothelialized. That's a fancy doctor's word for tissue encases it. It creates scar tissue and it gets immobilized to where it's stationary and it's not going to move.

And you will hear evidence that because of that, struts in the pulmonary arteries are not considered to be significant problems. The medical literature indicates that as many as 95 percent of those cases, if not more, result in asymptomatic patients, patients that never have a symptom attributed to that strut. 03:36PM

And even afterwards, Ms. Jones has still had problems with her gastric bleeding and had -- was hospitalized in 2016, a little over two years ago, for another episode of gastric bleeding. And as the stipulation read by Judge Campbell indicated, Ms. Jones has had no further medical treatment of any sort since March of 2016. 03:36PM 03:37PM

Her doctors have not attributed any physical symptoms to her filter or to the fractured strut. In fact, her doctor called it an incidental finding, a finding they just happened to see the fracture in the filter when they were doing a chest X-ray for other issues. Her doctors have not identified any symptoms she has related to that strut. And even the doctor who didn't treat her but the plaintiffs had paid as an expert witness who is going to come and testify, even the paid expert says that, at most, the risk of future complications from that strut in her pulmonary artery are only 1 percent. 03:37PM 03:38PM

Now, let's talk about the plaintiff's burden, what they have to show to recover in this case. And again, it is the plaintiff's burden by a preponderance of the evidence to prove their case.

She is going to attempt to prove an alleged design defect, that something about the Eclipse Filter was defective in how it was designed. She's going to allege a warning defect that Bard somehow did not adequately warn doctors who are the people we are charged with warning, about the risks with this device. She's going to have to prove under the law that one of these alleged defects, if they occurred, was the cause of her injuries, of an injury to her. And she's going to have to prove damages as a result of that. 03:38PM 03:38PM

Let's look first at design. And again, in assessing the design of the Eclipse Filter, the evidence will focus on the risks of the filter and the benefits. And ultimately, you will be asked as a jury to weigh those risks and those benefits. We already talked about the danger of pulmonary embolism and what a major health threat it is in this country. Up to 30 percent of people that have a recurrent or second pulmonary embolism die of that. Even in anticoagulated patients, people that are on blood thinners, as many as 5 percent of those people on blood thinners die when they have a second pulmonary embolism. 03:39PM 03:39PM

But only .036 percent, according to the reports and 03:39PM

data of patients who received a Bard filter, even suffer a recurrent or second pulmonary embolism. And an even smaller number of patients who received a Bard filter suffer a fatal pulmonary embolism.

What do the statistics mean? I have never been very good particularly when you get into a .00 something percent. So I tried to come up with a graphic that shows. Here's a graphic depicting 300,000 Americans dying every year from a second pulmonary embolism. 5 percent of those people on the anticoagulation will nonetheless die from another pulmonary embolism. Only 59 people, according to the data of 300,000 with a Bard filter will even have a subsequent PE. And according to the data, only 16 with a Bard filter died because of a subsequent PE. 03:40PM 03:40PM

I submit to you, Ladies and Gentlemen, that that evidence is powerful as to a lifesaving benefit of the device. It shows that these devices are as high as 99.99 percent effective. Even the plaintiff's own experts have admitted, and you will hear testimony from them during the course of this trial, that IVC filters, such as the Eclipse Filter, are lifesaving devices. 03:41PM 03:41PM

Now, these filters do have risks. And I want to be frank with you and talk about those risks. There are complications. But why do the doctors use them knowing that they have these risks? Because they are potentially lifesaving 03:41PM

devices. You may say why do they have complications? Why do they fracture? Why do they migrate in a certain number of instances? Why do they penetrate? Why do they tilt?

Well, part of the reason, this is a very harsh and dynamic environment in the body. The inferior vena cava is not just a standard -- it looks like a tree trunk in all our drawings. It's not a standard stationary tree trunk. It is moving as we move. It is compressing. When we cough it compresses or expands. Movement, twisting, there are just all sorts of stresses being placed on the inferior vena cava and, therefore, on any device implanted in it. And the engineers have a daunting task to try to develop this sort of device that can be placed in this unfriendly environment and still remain as stable as possible to perform its lifesaving function. 03:42PM 03:42PM

And to make these devices retrievable, they have to weigh many competing issues. They have to design the anchors carefully. If you make them too strong, the filter is difficult to retrieve. If you make them too weak, it's easier for the filter to migrate or tilt. With the arms and legs, if you make them too thick or rigid, it's difficult to retrieve the catheter. It can't fit into the retrieval sheath or catheter it's compressed in. If you make them too thin or flexible it's easier to retrieve but it may fracture. 03:42PM 03:43PM

Same thing with arms and legs span. You have to weigh the design considerations. But if you make them too much one 03:43PM

way, you have a problem and if you make them too much the other way, you have a problem. And you are going to hear from the engineers, from Andrzej Chanduszko, from Rob Carr and others at Bard and the work they have devoted their lives to trying to assess these design issues to learn about this harsh and dynamic environment and to develop and improve year in and year out these lifesaving devices. 03:43PM

Now, doctors recognize, just like Bard does, that no matter how hard Bard attempts to, or any manufacturer attempts to, and Bard is by no means the only manufacturer of IVC filters, there are going to be complications with a certain number of them. Those complications include things such as fracture, tilt, penetration, migration. There is a group, the leading also group of doctors that implant these filters are interventional radiologists. And their main professional society is the Society of Interventional Radiology, actually called SIR. And they develop guidelines as early as 2001 regarding these filters. And you can see the lead author there, the head of the task force that came up with these guidelines is Dr. Clement Grassi, who at the time was a doctor at Harvard in Boston. And Dr. Grassi consults with us. And he's going to come in this courtroom in a couple of weeks and testify and explain to you the process that went into developing these guidelines. 03:44PM 03:44PM 03:45PM

And in these -- and they have been updated several 03:45PM

times since Dr. Grassi's pioneering work in the original ones. And these guidelines recognize, as the medical community do, that there are complications with these devices, all devices, not just Bard's.

And these guidelines show, if you will look at the third line, that filter fracture, the complication that Ms. Jones unfortunately sustained, occur in 2 to 10 percent of patients. Why the doctors keep implanting these in patients when they know, and the medical community knows they can fracture that often, the evidence will show, you because they decide, day in and day out, that the life-threatening nature of a pulmonary embolism is so great that the lifesaving benefit of the device outweighs its risks. 03:45PM 03:46PM

Now, these IVC filters are not just somebody snaps their fingers at Bard Peripheral in Tempe and starts selling them. It is a long process to get clearance from the FDA to sell these. Bard must demonstrate that a device that is developing and wants to sell is substantially equivalent to an earlier already cleared device. 03:46PM

Now, the FDA has a wealth of experience with inferior vena cava filters. Two decades ago in 1996 the FDA carefully weighed the risks and benefits of all these devices, not looking at Bard filters but all filters. And the FDA recognized in assessing these devices that all filters present the risk of complications and recognized that many of these 03:46PM 03:47PM

complications can be potentially life threatening. And the FDA recognized the same complications that Mr. O'Connor was talking about. They recognized that filters migrate and said that migration was reported in filters 6 to 53 percent of the time. They recognized that filters penetrated and tilted, and they recognized that filters fractured in as much as, according to their data, 2 percent of the time. 03:47PM

But the FDA also noted that pulmonary embolism is a serious clinical issue, just like the Surgeon General did more recently. And they concluded that given the potential benefits, the risk of illness or injury presented by these devices is not unreasonable. In other words, the risks are outweighed by the benefits. 03:48PM

And after that the FDA developed a guidance document. It was a document made published in the Federal Register for use and consultation by manufacturers such as Bard. And it provided the agency's recommendations of what needed to be done to gain clearance of an IVC filter. And it required, or suggested, very detailed studies that it thought should be done involving deployment, clot trapping ability, filter fraction, perforation, migration, and more. 03:48PM

And that's exactly what Bard did. Bard conducted, and you will see, study after study after study, first of the Recovery Filter, then of the G2 Filter, then of the Eclipse Filter. And those studies showed improvement along the way. 03:49PM

Here's just one example showing that the fracture resistance for the G2 Filter, look how much greater, according to the tests performed, the fracture resistance for the G2 Filter which is depicted on the right, it's called modified RF or Recovery Filter there, was than the initial Recovery Filter. 03:49PM
Learning from the clinical experience with the first generation filter, Bard improved it and tested it and the test demonstrated the improvement.

And there were just many examples. If we had to go through all the testing we would be here for hours. We would 03:50PM all be asleep, myself included. But the studies included migration, fracture, fatigue, simulated use, et cetera, et cetera. And that's just on the G2. The same things were done with the Recovery Filter.

And throughout this process, Bard communicated 03:50PM extensively with the FDA. It submitted all its test data to the FDA and it answered multiple questions from the FDA. Mr. O'Connor says this is an honor program. You will see the evidence that the FDA simply did not see the application and stamp it cleared. It asked detailed questions. It asked for 03:50PM additional test results. It asked for more tests to be performed. It required a short clinical study with Recovery Filter. It required a longer clinical study with the G2 Filter.

Ultimately, as I indicated earlier, the FDA cleared 03:51PM

the Recovery Filter on two occasions. It cleared the G2 three times. It cleared the G2X, the third generation filter, and then Bard set about to develop the Eclipse to electropolish the filter. And it conducted a whole new battery of tests. It tested filter arm fatigue, and that showed a 60 percent increase in cyclic fatigue life. In other words, the durability of the Eclipse Filter was 60 percent improved over the G2 Filter which, as you saw, was way improved over the Recovery Filter. 03:51PM

There was more testing. This tested the fatigue life of the electropolish Eclipse wire. The Eclipse project was initially called Vail, but that was same thing that ultimately became Eclipse. 03:51PM

Look at the improvement over the G2, or G2X in this instance. 77 percent; 101 percent; 78 percent. Evidence, once again, that the evolution and design changes being made by this company over the years were making a good product better every step of the way. 03:52PM

Even more testing, corrosion. And you will hear the engineers talk about all this testing. Ultimately, the FDA cleared the Eclipse Filter on January 14 of 2010. And later that same year, as the newest generation filter manufactured by Bard with this long in dwell time where it could be kept in the body for a long time and ultimately retrieved as it was five years later in Ms. Jones' case, her doctor decided to implant 03:52PM

that in her.

The plaintiffs talk about the Simon Nitinol Filter, but again, that's not an alternative to the Eclipse Filter. It is a permanent filter that never could have been removed from her. And doctors don't like permanent filters. This is the sales history over the years of Bard's retrievable filters compared to the Simon Nitinol Filter. The lower line is the permanent filter. You can see how much doctors prefer the retrievable filters because then they have the option to remove these devices. 03:53PM

The plaintiff's evidence that you have heard and will hear over the next week or two is not really concerning the Eclipse Filter. It's focused on the earlier generations. It will be presented by well-paid experts. It will consist of a few isolated documents such as those you saw today, which we submit are taken out of context. One example will be they showed you a document that says that the occurrence of migration with the G2 is unacceptable. The evidence will show that that assessment was done internally, early in the life of that product after only 13 reports. 03:54PM

So we will present you evidence throughout to place these individual documents in context and will cite a number of medical articles. We're going to bring to you a number of epidemiologists and clinicians to talk about the medical wealth of literature. And we submit the evidence we have will be 03:54PM

contradicted by the whole story and the numbers. And that ultimately in determining the design of this filter, the low risk will be demonstrated by the evidence of the small complication rate associated with the Eclipse Filter.

Now, let's talk a little bit about warning, the plaintiff's claim that we failed to warn the doctors. But in every single Eclipse Filter sold, in that package was what's called an Instructions For Use, an IFU. That IFU warns the doctor specifically about the complications associated with all filters, including the Eclipse. And all these doctors are going to tell you is that they didn't need to read the IFU to know about these. All they have to do are read the medical journals that come across their desk every month. These are well known in the medical community. 03:55PM 03:55PM

But nonetheless, in abundance of caution, Bard warns. It warns that movement, migration, or tilt of the filter are known complications; that migration of filters to the heart or lungs have been reported. There have been reports of caudal migration, or downward migration of the filter. The IFU warns specifically about what occurred with Ms. Jones, that filter fractures are a known complication. There have been some reports of serious pulmonary or cardiac complications with vena cava filters requiring the retrieval of the fragment. And Bard warned about perforation or other acute damage. 03:55PM 03:56PM

So all the complaints the plaintiffs have are 03:56PM

concluded and warned about in the IFU: Migration, fracture, tilt, perforation. And Bard didn't leave anything to chance. The IFU specifically reminded doctors what they already know, that unfortunately, in a very small number of patients, these complications can be serious. 03:57PM

Bard told the doctors that all of the above complications may be associated with serious adverse events such as medical intervention and/or death. And they also, because of that, because that risk of complication is there with all filters, Bard warned doctors that they need to 03:57PM consider the risk/benefit ratio of any of these complications and weigh that against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism, in other words, encouraging every doctor, just like Ms. Jones' doctors, to make that risk/benefit calculation. 03:57PM

Bard also reminded doctors that the SIR, the Society of Interventional Radiologists, recommended these patients be monitored on an ongoing basis to see if the filters need to be retrieved. But Bard didn't just do the IFU, even though that IFU was in every single package that went out to a doctor with 03:58PM one of these devices. The evidence will show that Bard also developed a patient brochure and gave this patient brochure to doctors and gave them the option, if they thought it appropriate for their patient, to provide that brochure to the patient. 03:58PM

Bard is a medical device manufacturer. It does not practice machine. Our doctors practice medicine. And the evidence will demonstrate that in this country the doctors make the decision on what to give patients and what to do and Bard does not do that, nor does or can any medical device manufacturer. But Bard gave this resource to doctors who wanted to use it. And in that brochure, Bard specifically noted, look at the bullet point: The entire filter or pieces of the filter may break loose and travel to the heart and lungs causing injury or death. You may need to have additional surgery to retrieve the filter or pieces if they break loose. 03:58PM 03:59PM

Again, Bard's not hiding anything. But the plaintiffs will claim that somehow there's evidence, despite the numbers, that Bard's filters fracture or perforate or migrate more than others and said we should have put in the IFU data concerning these rates. 03:59PM

Oh. I'm sorry. Before I talk about the rates, I meant to mention that Bard submitted this patient brochure to the FDA for its review and clearance. In a separate letter, the FDA came -- here's the submission. It says: The primary modification from the original Eclipse, the predicate device, is the addition of a patient brochure and implant card to the labeler. 03:59PM

The FDA cleared the submission of the patient brochure, but the plaintiffs say you should have put complaint 04:00PM

data, complication data, rates. The only data we have concerning other manufacturers' products comes from the FDA database called MAUDE. It's an acronym for Manufacturers and Users Data. It's something where people, doctors, have the right to voluntarily report any complications with devices. 04:00PM
Manufacturers, when we learn about them, we are required to. But doctors are advised to, and it's voluntary whether they do.

But Bard -- I mean, the FDA makes it clear that this data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates 04:01PM across devices. So the evidence will demonstrate that the FDA tells us we cannot do exactly what the plaintiffs claim we should do.

As I mentioned earlier, the plaintiffs also will need to show causation. The principal complaint that Ms. Jones 04:01PM attributes to the filter is fatigue. And as I indicated to you, her medical records will demonstrate that she was complaining of fatigue and she was diagnosed with anemia related to her long history of gastric bleeding prior to ever receiving the filter. No treating doctor will say that she has 04:01PM any symptoms or has ever had any symptoms associated with the filter. So we submit that the evidence will not demonstrate that any alleged defect caused an injury here.

Well, you will say, she has this retained strut. You are going to hear experts talking about the medical literature 04:02PM

with regard to retained struts like struts in the pulmonary artery like Ms. Jones has.

This is an important study from the University of Pennsylvania looking at 65 patients with fractured filters. And these aren't all Bard filters, they are all different manufacturers' filters, and concluded that these fragments present little risk of complications or symptoms. Another study indicates that there's no reports in medical literature of clinically significant consequences, and that fractured struts in the pulmonary artery are thought to be asymptomatic causing no symptoms and usually clinically insignificant. 04:02PM 04:03PM

And there will be absolutely no evidence that anything to do with the warnings provided by Bard had any causal relationship with the choices her doctors made to put in this filter. And then lastly, it will be her burden to show damages. 04:03PM

Ladies and Gentlemen, as you hear the evidence and what will be a long, I know, three weeks, and we do appreciate your time and dedication to helping us resolve this dispute, we would ask that you keep an open mind, that every step of the way you wait to hear the whole story. Because the plaintiffs have the burden of proof, they will always go first. They will present their opening statement before I do. They will put on their witnesses before I do. They will give their closing argument before I can. And we ask that you keep an open mind 04:03PM 04:04PM

throughout the whole process and hear every step of the way to hear the whole story.

Again, Ladies and Gentlemen, the evidence at issue in this case that the evidence will focus on is not whether we have sympathy for Ms. Jones. Because we're all people. We do. 04:04PM
Nobody wants anybody to have a medical problem or a complication. But the evidence will focus on the risk/benefit and whether this lifesaving device, its potential to save her life after two reports of DVT and a need for surgery because of gastric bleeding, whether that benefit outweighed the very 04:05PM
small risk of a complication.

We submit to you that when you hear all the evidence, that evidence will demonstrate that, indeed, those benefits outweighed the risks. And then Ladies and Gentlemen, at the conclusion of the entire trial, after you have heard both 04:05PM
sides, and after you have heard the whole story, we will come back here in closing argument and ask you, as sympathetic jurors, but impartial jurors, to render a verdict in favor of my clients, C.R. Bard and Bard Peripheral Vascular.

Thank you very much for your time and attention. 04:05PM

THE COURT: All right. Thank you, Mr. North.

Ladies and Gentlemen, as we indicated we're going to go until 4:30. We're going to try to push through to 4:30 every day just to make sure we finish this trial within the amount of time that we have told you we would. 04:06PM

So the next step is for the plaintiff to begin presenting evidence.

MR. O'CONNOR: We need to approach for a moment, Your Honor.

THE COURT: Go ahead and stand up. I will talk to the lawyers just a moment. 04:06PM

(Discussion was had at sidebar out of the hearing of the jury:)

MR. LOPEZ: Well, I told you I'd be listening.

THE COURT: Let me interrupt you. Is this something about the opening? 04:06PM

MR. O'CONNOR: Yes.

THE COURT: Let's not do it now.

MR. LOPEZ: If it affects a document we have to redact, go back and unredact. 04:06PM

THE COURT: Are you going to be showing a document in the next 20 minutes that's been redacted?

MR. LOPEZ: I really don't know, Judge.

THE COURT: If we don't know seems to me we shouldn't take time now from the jury. 04:06PM

MR. LOPEZ: I agree. I'd like to get started. If this happens that we can show, actually show it unredacted, we can deal with it later.

THE COURT: Let's deal with that after the jury is excused. 04:07PM

(In open court.)

THE COURT: So plaintiff's counsel, you are going to show a deposition, is that right?

MR. O'CONNOR: That's correct.

THE COURT: Ladies and Gentlemen, let me give you one more instruction about what you are about to see. 04:07PM

You are going to see a videotape deposition for the next 22 minutes before we break. A deposition is the sworn testimony of a witness taken before a trial. The witness is placed under oath to tell the truth, and lawyers for each party may ask questions. The questions and answers are recorded both by a court reporter and on videotape. And what you will be seeing is the videotape. And when a person is unavailable to testify during the trial then the deposition can be used during the trial. 04:07PM 04:08PM

So you will see the deposition of a number of witnesses. Before we start them, typically, and I assume this is what you are going to do, Mr. Clark, will be a brief set of introductory facts shared with you that the parties have agreed on to tell you who the witness is. And to the best of your ability, you should consider deposition testimony presented in court in lieu of live testimony in the same way as if the witness had been presented to testify. It's essentially the same evidence, even though you have to watch it by videotape. 04:08PM

I will also say that it's likely true during the 04:08PM

course of this trial that you are going to see more videotape testimony than you would like. I can assure you the parties have tried to pare that down to a minimum, but there are some witnesses who just can't come to Arizona for this trial and it's necessary to show their testimony via videotape. 04:08PM

Mr. Clark.

MR. CLARK: Your Honor, at this point the plaintiffs would like to move for admission of the following exhibits and then after that, provide a brief background summary.

The exhibits -- 04:09PM

THE COURT: Excuse me, Mr. Clark. Do these need to come in before the deposition?

MR. CLARK: They do, Your Honor.

And for convenience could I approach the lectern?

THE COURT: Yeah. Absolutely. 04:09PM

MR. CLARK: The exhibits are Trial Exhibit 1948 which corresponds to Deposition Exhibit 2; 1950, which is deposition Exhibit 2; 1951 --

THE COURT: You said 1948 was Exhibit 2.

MR. CLARK: I apologize. I misspoke. 1950 is 04:09PM Deposition Exhibit 4.

THE COURT: All right.

MR. CLARK: 1951, which is deposition Exhibit 5; 2244, which is Deposition Exhibit 7; 1940, which is Deposition Exhibit 11; 1941, which is Deposition Exhibit 12; 1944, which 04:10PM

is Deposition Exhibit 15; 1946.

THE COURT: Hold on just a minute. 1944 was 15?

MR. CLARK: Correct.

THE COURT: All right.

MR. CLARK: 1946, which is 17; 1947, which is 19; 735, which is 20; 1949, which is 21. 04:10PM

THE COURT: You have already said 1941. What was the last one you listed?

MR. CLARK: 49, Your Honor.

THE COURT: 1949. And that is -- 04:10PM

MR. CLARK: 21.

THE COURT: Okay. Is there any objection to the admission of those exhibits?

MS. HELM: Your Honor, no objection with the caveat that 2244, 1940, 1941, and 1944 are subject to the Court's prior order and the parties have addressed those. 04:10PM

THE COURT: Okay. That's fine. I will admit all of those exhibits in evidence. And you can play -- well, why don't you give us the summary and then we'll play the deposition. 04:11PM

MR. CLARK: Gin Schultz received her Bachelor's degree in chemical engineering from the University of Missouri in 1981 and received a Master's degree in business administration in 2003. She joined Bard Peripheral Vascular or BPV in October of 2005 as vice president of quality assurance. In this role she 04:11PM

was responsible for overseeing the quality systems, ensuring BPV was complying with regulations, and hiring and managing the quality assurance staff.

In 2011 Ms. Schultz transferred to C.R. Bard to be the vice president of quality operations, a role from which she just recently retired. Prior to working at BPV she had a 15-year career at Johnson & Johnson in its medical device subsidiaries where she held various positions, including manager of quality and compliance services. 04:11PM

(Video deposition of witness Gin Schultz played in open court.) 04:12PM

THE COURT: Counsel, let's stop the depo there, please.

All right. Ladies and Gentlemen, we have reached 4:30. We'll break for the day. Just leave your notes on your chair. We will be here and ready to start right at 9:00 tomorrow, so please factor that in in your commute down. Take into account traffic as well. Hopefully you will all be here at 9 and we can get in and get started and stay on time. 04:29PM

And please remember again what I have already said several times not to do any research or look into any facts related to the case. 04:30PM

Counsel, anything else we need to address before we excuse the jury?

MR. O'CONNOR: Nothing with the jury, Your Honor. 04:30PM

MR. NORTH: Nothing, Your Honor.

THE COURT: Okay. We'll see you tomorrow morning at 9. Thank you very much.

(Jury out at 4:30 p.m.)

THE COURT: All right. Go ahead and be seated, counsel. 04:30PM

For your information, as of the end of today plaintiff has used one hour and 25 -- I'm sorry -- one hour and 29 minutes. Defendants have used one hour and four minutes.

Mr. Lopez, you wanted to raise an issue at sidebar and we decided to address that after we let the jury go. 04:31PM

MR. LOPEZ: Yes, Your Honor.

As I advised the Court, I would be listening intently with respect to any matter that came up before the jury that might make fatalities as a result of cephalad migrations relevant in the case. 04:31PM I will say this, Mr. North made a big deal more than once that -- and this was not restricted to the Eclipse Filter. This was all Bard filters. Only 16 deaths out of, I forget. I didn't write down the number. It was some number over 300,000 units sold, they were all Bard filters. 04:31PM That the fatality rate for all Bard filters was .0098. And then he said when he was going through the IFU, as if they were doing something they didn't even need to do, we even reported death in the IFU.

And for that to come in front of the jury without an 04:32PM

explanation as to why maybe death was there -- and one of the things, Your Honor, is this -- I assume that was an Eclipse IFU.

MR. NORTH: Uh-huh.

MR. LOPEZ: There were no deaths as a result of the Eclipse Filter, as far as I know. I think that's one of the arguments that they made. 04:32PM

And that is fairly strong proof that these IFUs, these warnings, they start from the first product in a family of products. That would have been the Recovery Filter. And if you come out with another generation, G2, and just because there's not been a report for G2, and if you have had 19 deaths with the Recovery Filter, that's in the label. That's our position. That should have been in the label. They didn't differentiate that they made that label as if that was -- it's what we call a class warning. That should not have been a class warning. 04:32PM 04:33PM

So three times during his opening statement he talked about only 16 deaths, only .0098 fatality rate, and we even reported death. And I think that opens the door, Your Honor. We now have to be able to explain to the jury, show the jury, that they shouldn't be proud of the low number of deaths that have been reported with all Bard filters, nor should they be proud that they included death in their IFU warning, that there's a really good reason why death is in there. And 04:33PM 04:33PM

there's another explanation, or I'm sorry, there are other reasons why there are fatalities related to Bard filters. And that's the cephalad migrations to the heart.

THE COURT: So what are you requesting, Mr. Lopez?

MR. LOPEZ: I'm requesting that we now have an opportunity to put in front of the jury that there have been deaths caused by a design of a predecessor device to the Eclipse and that the fatality rate for at least that filter maybe that increases the fatality rate by double or triple. Now instead of them being able to brag about there's only been 16 deaths from PE reported with all Bard filters, the number is now 35. 04:34PM 04:34PM

So, I mean, that's what's fair. That's what the jury should know. They have been misled in opening statement about the safety of all Bard filters as relates to death three times. 04:34PM

THE COURT: Mr. North.

MR. NORTH: Two things, Your Honor: First of all, the slides that Mr. Lopez is talking about are the same slides we talked about at the beginning when they made their objections. Those were not focused on complication rates. Those were focused on efficacy. The slide specifically talked about the number of patients that die from recurrent pulmonary embolism than those who die from recurrent pulmonary embolism while on anticoagulation and then the number of reports of people who died from recurrent pulmonary embolism with Bard filters. It 04:35PM 04:35PM

was talking about the efficacy and the lifesaving potential of the filters and not the complication rate.

Secondly, with regard to --

THE COURT: Hold on just a minute.

Is it Slide 46 that you are referring to? 04:35PM

MR. NORTH: I believe that's correct, Your Honor. Mine are misnumbered. I'm having a hard time with the numbers.

THE COURT: On Slide 46 it says only 16, then paren, .0098 percent, close paren, with a Bard filter die because of a subsequent PE. 04:36PM

MR. NORTH: Right, Your Honor, which was the point I was making. We were comparing that to the number of people that had subsequent PEs that have reports with Bard filters and the previous slide talked about the number of people anticoagulated who died from the subsequent PE. And then the 04:37PM first chart showed how many people total died of a subsequent PE talking about efficacy again.

THE COURT: So the 16 deaths are people who died from a pulmonary embolism after receiving a Bard filter?

MR. NORTH: Yes, Your Honor. And I'm sure some of 04:37PM those are wrapped up in the ones he's talking about the migration. But the focus was on whether the filter was working, the efficacy, not what the complication rate was.

THE COURT: All right. Did you have -- I interrupted you. Did you have other -- 04:37PM

MR. NORTH: Yes, Your Honor. I also wanted to talk about the Eclipse IFU. I think that that statement in there is entirely consistent with the Court's ruling which has told the plaintiffs repeatedly that they can present evidence that these complications have the potential for death. They just can't talk about the Recovery Filter cephalad migration-specific incidents. That's what the Eclipse IFU did. It said these complications have the potential to cause death, which is exactly what the Court has said they can be put in. I just put that evidence in to say we warned about that. 04:37PM 04:38PM

THE COURT: All right. Anything else?

MR. NORTH: Nothing else.

THE COURT: Mr. Lopez, did you have other thoughts?

MR. LOPEZ: Yes, Your Honor. Now, as you know, the majority of the cephalad migrations had a clot that were of the quality of a clot that would cause a PE. And those are not, despite what Mr. North just stated, called PE deaths when it's reported because it never gets to the lung. So now we've got 19 more deaths caused by, I don't know whether all of them. I don't want to misrepresent to the Court. I will just say the majority of those 19. I think there have been more since. I'm talking about before it was taken off the market. I think the number is 27 now. 04:38PM 04:38PM

But in the overwhelming majority of those, there are, let's say, 19 or 20 where it was -- there was a clot that never 04:39PM

made it to the lung, and therefore, there is actually double the number, maybe triple the number of deaths that he just told the jury were caused by a PE with any Bard filter. You know why? Because of the device and the clot, they were too big to pass through the heart and go to the lungs and cause a PE. 04:39PM

And again, Your Honor, this is a regulatory case. The FDA is here in all its glory, and we have a right to put on evidence that the labeling in the Recovery Filter is inadequate and misleading and false from the standpoint of the way they mention death. 04:39PM

THE COURT: In the Recovery Filter?

MR. LOPEZ: In the Recovery. Because, Your Honor, regulatory -- same thing with drugs, but especially for devices that are not only in the same class, but this is the same family. If you look at the warnings they carry themselves 04:40PM through. The FDA doesn't get involved in warnings on a 510(k) device. These are their warnings.

THE COURT: Mr. Lopez, what I'm not understanding is why an inadequacy in the Recovery Filter warning is relevant to your failure to warn claim about the Eclipse Filter. 04:40PM

MR. LOPEZ: Because it should have been in the Eclipse IFU, because it is in the same family of devices. They should have had in that warning that these devices, this family of conical devices, has had a certain number of deaths, not just death as a death, I mean, that could be from anything. The 04:40PM

fact that they had a death caused by a bad design of their product, they had a fix that didn't stay where they put it and it was caused to dislodge under the circumstances for which it was intended, to actually save a person's life actually resulted in death. That gets carried through to device after device after device. 04:41PM

THE COURT: Let me make sure I understand your point. I think what you are saying is, and correct me if I'm wrong, you want to argue to this jury that the Eclipse Filter warning was defective, was inadequate because it didn't describe deaths that had occurred with the Recovery Filter by a method of migration that had been eliminated after the Recovery Filter was taken off the market. 04:41PM

MR. LOPEZ: Well, okay. I think -- I'm not sure I would word the warning that way. 04:41PM

THE COURT: I know you wouldn't word it that way, but isn't that the point? Aren't you saying they should have told Eclipse Filter doctors that there were deaths caused by an earlier generation of filter by a method of migration that no longer happens with Eclipse Filters? 04:42PM

MR. LOPEZ: But we don't know that, though, Judge. That's the point.

THE COURT: That's what I have asked for is evidence of cephalad migration deaths with Eclipse Filters, and we have been over this ground a lot but there hasn't been any evidence 04:42PM

of that.

MR. LOPEZ: But there may never -- there could be 20 of them that have happened in the last five years and we may not know about it. There's no tracking, there's no survey, there's no monitoring of these people. They haven't paid for a surveyor to do a registry, we don't know. But what we do know is that the Eclipse Filter was borne out of the design of the Recovery Filter. And it suggests that the Eclipse kind of stands on its own. Mr. Carr himself says that the Eclipse is the G2 Filter that we electropolished. 04:42PM

THE COURT: I understand all those points because we have talked about that a lot. Just to make sure, what you are saying is based on the opening statement I should allow you to put in evidence of Recovery Filter cephalad migration deaths.

MR. LOPEZ: Yes. In other words, there's three reasons. Number one is they bragged about the fact that, in his words, we even put in death, in other words, suggesting to the jury that our filters have never had a history of having put in death but we still put it in the label. The truth is that label should have details in it about all of the predecessor devices in that family. That's our position. And if you see the history of what they have done with their IFU or the warnings or precautions, even though every device is different, whether one has more perforations, one has more fractures, less fractures, more deaths, migrations, caudal, 04:43PM

it's the same warning because it all started with the Recovery Filter being an inadequate warning.

THE COURT: What are your second and third points?

MR. LOPEZ: Second and third points are that he said all Bard filters, there have only been 16 deaths by pulmonary embolism and that the rate is .0998 fatality and all Bard filters have been effective in 99. something, I forget what the number was, in all other places where it's been implanted. 04:44PM

That is a false and misleading statement to the jury. That is a 403 statement that we have right now to explain that it was, that, no there have been more than 16 deaths from PE, or there have been maybe 16 PE deaths but there have been another 19 that didn't count because the clot never got to the lung because it stopped in the heart with the device wrapped around the clot. 04:44PM

THE COURT: What is your third point?

MR. LOPEZ: Deals with the same thing as the fatality rate.

THE COURT: Okay.

MR. LOPEZ: Again, I know we have made this argument before, Judge. But again, this is a lifesaving device. I mean he's talking about filters in general. He didn't say the Eclipse was a lifesaving device because there's no evidence of that. We know that. But he says that Bard -- that filters are lifesaving devices. And as soon as you say that, I think it 04:45PM

opens to door once again to the fact that, no, the only evidence that exists for Bard filters, the only evidence, despite how many times they say this, is that it actually caused death. They know that. Their own witnesses say that.

THE COURT: I understand that point. Let me ask you two other questions, Mr. Lopez: Have you disclosed in this case an expert who will say that the Eclipse Filter IFU should have disclosed Recovery Filter cephalad migration deaths? 04:45PM

MR. LOPEZ: No. I doubt it. I'm saying no but I can -- I haven't read Dr. Parisian's 800-page report. 04:46PM

THE COURT: You are not aware of any?

MR. LOPEZ: No. But we can still argue that, Judge.

THE COURT: Are you aware of any legal standard FDA guidance or regulation that says, in effect, that Eclipse Filter warning should disclose deaths from an earlier version by a different methodology that hasn't been shown to occur? 04:46PM

MR. LOPEZ: The best I have, Judge, is what was ever in the Recovery Filter, despite the differences that existed after that, are in the Eclipse Filter.

THE COURT: Well -- 04:46PM

MR. LOPEZ: Warning.

THE COURT: When you say the best you have --

MR. LOPEZ: In other words, I think that's pretty good circumstantial evidence that whatever warning the first in line has irrespective of the performance of the subsequent devices, 04:47PM

the G2, the G2X, the Eclipse, I haven't looked at the Meridian. Maybe that's changed. It's the same warning.

So we certainly have put on evidence that the Recovery Filter should have said something much different. And if you follow the same pattern of having to carry through the same warning that you have in the -- in, you know, the -- I don't know what to call it, the mother device or the original device or the device out of which all these other devices were borne, then yes. They wouldn't all of a sudden take that out in subsequent warnings because they don't -- Your Honor, the Eclipse warning does not say the Eclipse Filter. It talks about filters. That's the problem we have with it, is that it's a class -- 04:47PM 04:47PM

THE COURT: I missed your last sentence.

MR. LOPEZ: It's a class warning. In other words, this is another situation where it's all filters, all filters, all filters. I know what you Your Honor has said, is this is about the Eclipse. Well, that warning is not about the Eclipse Filter. It goes back and it covers the history of warnings of events that happen in all filters. And that's one of the problems with the way they argue this case. They never talk about Bard filters. They talk about IVC filters, all filters. 04:48PM 04:48PM

I think the most troubling thing is we even report death and the low fatality rate and the low PE rate has now misled this jury about the reality of all filters. 04:48PM

THE COURT: I understand.

Mr. North, what evidence are we going to put before the jury that will state what your chart showed at 16 deaths at a .0098 rate, what witness is going to say that?

MR. NORTH: Your Honor, I believe it is Mr. Modra or Mr. Carr. I'm going to have to go back and check. But we did go through that to make sure there was somebody to support that last time. I do believe it's Mr. Modra and it's based upon the complaint data, the same that gives us the fracture rate and this and that. 04:49PM

THE COURT: Do you agree that if Mr. Modra or Mr. Carr testifies to those facts to the jury plaintiff's counsel can cross-examine them as to what deaths they counted, where they got the deaths, whether they took all deaths into effect or into account? 04:49PM

MR. NORTH: Yes, Your Honor. I mean, I think that's fair.

THE COURT: Do you think they can ask does this count cephalad migration deaths from the Recovery Filter?

MR. NORTH: I don't know that they would have to do that to make the same point. I think they could ask for all reported deaths. 04:49PM

THE COURT: Would there be anything improper in that cross-examination in your view, since you are putting out that death number? 04:50PM

MR. NORTH: Your Honor, I don't think there would be anything improper of the cross-examination of the fact of that as far as the statistics to challenge whether the statistic is accurate. But I don't think that opens the door to go into all of the detailed evidence that we heard about at the last trial. 04:50PM

THE COURT: Okay. I understand the parties' positions. I want to think about this issue a bit more.

Mr. Combs, there was an exhibit that we needed to address?

MR. COMBS: Yes, Your Honor. I think it's 1035. I think I have a copy, Your Honor, if you want to look at it. 04:50PM

THE COURT: If I need to rule.

MR. COMBS: May I approach?

THE COURT: Yeah.

MR. COMBS: And, Your Honor, as we discussed earlier we're just looking to move this into evidence over 401, 402, and 403 objections. Those are the only objections Bard has offered to us. If they've got more then I haven't heard them yet. 04:51PM

THE COURT: Ms. Helm, are these relevancy and 403 objections? 04:51PM

MS. HELM: Your Honor, this document that they are tendering, they are seeking to admit it through the deposition of Mr. Greer. At least that's what was communicated to me. This is not an exhibit to Mr. Greer's deposition. 04:51PM

THE COURT: Well, but the question is, they could move it independent of that deposition into evidence. The question is, what is the objection you are making? Is it anything besides relevancy and 403?

MS. HELM: Your Honor, I'm not sure. The copy of the exhibit that I have has handwriting on it. And so I can't stipulate that this is a regularly-kept business record because I don't know how the handwriting got on page that has 5646 in the Bates number. 04:52PM

THE COURT: If that handwriting was removed is it only a relevancy and 403 objection? 04:52PM

MS. HELM: Yes, Your Honor.

THE COURT: Mr. Combs, go ahead on relevancy and 403.

MR. COMBS: We have talked a lot about cephalad migration and how that's different and distinct. This is a fracture document. And it goes to several issues dealing with fractures. And this is a fracture case. And it goes to show that they never fixed the problems of fractures going all the way back to 2004 that they are well aware despite design changes between the Recovery and G2. And it goes to damages as well. Just finding my highlighting, Your Honor. 04:52PM

On the second page, migration of metal fragments to the heart or lung presents the possibility of cardiac or pulmonary injury with serious clinical consequences.

THE COURT: Where are you reading? 04:53PM

MR. COMBS: Second to the bottom paragraph under, "Likelihood of harm if the problem occurs."

THE COURT: Okay. I see that.

MR. COMBS: So I think a different iteration of this we even showed in opening that had similar language. But it's -- there's no way it could be -- the unfair prejudice could substantially outweigh its relevance. It's directly relevant to a number of issues in the case. 04:53PM

THE COURT: Okay.

MS. HELM: Your Honor, there may have been some confusion. It was communicated to me that they wanted to tender this with Mr. Greer's deposition and publish it with his deposition. I don't think it can be published with Mr. Greer's deposition because it's not discussed in that deposition. 04:53PM

I also, again, raise this issue of the handwritten notes on it. So subject to those two issues, we don't have an objection to it being admitted as long as the handwriting is redacted and it's not published during Mr. Greer or any deposition where it's not discussed. 04:54PM

THE COURT: So you agree then Mr. Combs or plaintiff's counsel can move it into evidence outside of a deposition? 04:54PM

MS. HELM: Yes, Your Honor.

THE COURT: Provided the handwriting is redacted?

MS. HELM: Yes, Your Honor, and that it not be published with any deposition in which it was not discussed. 04:54PM

THE COURT: Does that solve the problem, Mr. Combs?

MR. COMBS: Yes, Your Honor.

THE COURT: Anything else we need to talk about before we break?

MR. NORTH: One thing quickly, Your Honor. We have -- our service has been doing some research about the television advertising today. They still have not tracked down who actually did the one that we heard, but they have as part of their investigation determined that several dozen, it appears, ads have been aired or sponsored locally in the last three weeks by a Scottsdale firm by the name of The Goldwater Firm. They have filed cases in this MDL. They filed at least one or more cases in conjunction with a firm called the Capretz firm where the principal is Don Ledgard who is a former colleague of the Lopez firm. I'm not saying Mr. Lopez knows anything about this. 04:54PM 04:54PM 04:55PM

THE COURT: Hold on.

MR. NORTH: I'm not saying he knew anything about this. What I am saying is they have a way to get in touch with these people, to contact them to try to at least tap down this advertising during trial. 04:55PM

MR. LOPEZ: Let me -- first of all, I know Mr. Capretz because his office is in Orange County. Mr. Ledgard was a law clerk for me 20 years ago. I haven't spoken to him.

THE COURT: There's no connection. 04:55PM

MR. LOPEZ: It feels icky, Judge, when I hear stuff like that.

THE COURT: It's okay. Take a deep breath. This isn't going to affect me at all. What I'd like to do, because I think it creates risk in the trial, is see if we can get them not to run those ads while we have a jury in trial. 04:55PM

MR. LOPEZ: That's what I was going to tell you. I can tell you this. I can't speak for everybody, but Goldwater Firm has not been on one POC call. They are not involved in this thing. Mr. Capretz and Mr. Ledgard are not. 04:56PM

THE COURT: So they are not involved in any part of the plaintiff's group.

MR. LOPEZ: Nothing. I don't want to turn it round that I gave them advice or they called me one time on a Bard filter case. 04:56PM

THE COURT: I'm not asking it because I think you somehow are all behind it. But if they had any involvement in the plaintiff's group then I think I would have some leverage to say let's not do the advertisements during trial. If they don't, I can't order them to stop their advertisements. 04:56PM Supreme Court has said commercial speech is protected speech. I can't enter an order saying stop your ads during trial.

So seems to me if there isn't some involvement in the group that's trying the case there's no basis for me to tell them to stop. Do you see that differently, Mr. North? 04:57PM

MR. NORTH: I would like to do some further research as to how many cases in our database they are listed as having. Right now I just have one complaint. I think if they have a significant number of complaints that the calculus could be different. 04:57PM

THE COURT: I will leave it to you to raise the issue again. But based on what I have heard I'm not going to do anything at this point.

MR. LOPEZ: I offered earlier, I will work with Mr. North on trying to find out. I haven't had a chance to send this out to our POC yet because we have been involved all day with this trial. But I'm happy to hear it's not only someone who is not associated with our POC but I can tell you they have not participated in any aspect of it from day one. 04:57PM

THE COURT: All right. Let me know if there's more you think we should do. We'll plan to see you tomorrow morning at 8:30. 04:57PM

By the way, counsel. Sorry, Laurie. We started out today with the same practice we had in the Booker trial with not having the court reporter trying to transcribe the videotape testimony. I say that again because it's up to you to get on the record in the form of something you put into the docket exactly what portions of the depositions have been played so there's a clear record of what was presented to the jury. 04:58PM 04:58PM

MR. LOPEZ: So you need an actual written run -- we have been calling them runs -- that become part of the official record.

THE COURT: If we don't do that there's no record of what questions and answers were presented. So it seems to me it's incumbent on you to agree the following pages and lines of all of these depositions were played during Jones so there's a record for purposes of appeal of exactly what was presented to the jury. 04:58PM

MR. LOPEZ: Whatever we did, if we did it to the Court's satisfaction in Booker we'll do it the same way here. 04:58PM

THE COURT: I haven't seen what you did in Booker. I'm putting the burden on you to do that just because it's very difficult for a court reporter to transcribe the back and forth going on in a videotape. 04:59PM

MR. O'CONNOR: We will handle that.

MS. SMITH: In Booker I presented them --

THE COURT: Would you just identify for the court reporter.

MS. SMITH: Yes. Laura Smith. 04:59PM

In the Booker trial we were told similar instructions on the first day and the next day we brought all of the runs. And then we were told not to bring them and that we would hold onto them.

THE COURT: You brought them to whom? 04:59PM

MS. SMITH: I believe the court reporter.

THE COURT: There's nothing the court reporter can do with those. The point is I think you need to file them in the docket. And when you say the runs, what do you mean?

MS. SMITH: So the run is a transcript of what's played in the depo. 04:59PM

THE COURT: That's fine. But I think what you need to do is then file it in the docket. You can do it with a notice of filing, put it in the docket. That way it's in the Court's record. Giving it to the court reporter or to Nancy doesn't get it into the record. Does that make sense? 05:00PM

MS. SMITH: Yes. You are clear.

THE COURT: Let's do that. But if we've got to go back and do that in Booker we ought to do it so that the docket includes the runs of all the depositions played. 05:00PM

MS. SMITH: We'll have to go back and do that.

All right. See you in the morning at 8:30.

(Proceeding recessed at 5:00 p.m.)

C E R T I F I C A T E

I, LAURIE A. ADAMS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control.

DATED at Phoenix, Arizona, this 15th day of May, 2018.

s/Laurie A. Adams
_____
Laurie A. Adams, RMR, CRR